

Filed Pursuant to Rule 433
Registration No. 333-280273
Issuer Free Writing Prospectus dated July 2, 2024
Relating to Preliminary Prospectus dated July 1, 2024



KNOW LABS

TRANSFORMING NON-INVASIVE MEDICAL DIAGNOSTICS
(NYSE Amex:KNW)



Investor Overview
July 2024

DISCLOSURE

FREE WRITING PROSPECTUS

Filed pursuant to Rule 433 of the Securities Act of 1933, as amended. This Free Writing Prospectus related to the proposed public offering of shares of common stock of Know Labs Inc. (the "Company"), which are being registered on a Registration Statement on form S-1 (File No. 333-274350) (as amended, the "Registration Statement") filed with the United States Securities and Exchange Commission ("SEC"). The Registration Statement has not yet been declared effective by the SEC. Before you invest, you should read the preliminary prospectus in the Registration Statement (including the Risk Factors described therein) and other documents the Company has filed with the SEC for more complete information about the Company and the proposed offering. The Registration Statement is accessible through the following web link: https://www.sec.gov/Archives/edgar/data/1074828/000165495424008492/kown_s1a.htm

Alternatively, the Company and any underwriter or dealer participating in the proposed offering will arrange to send you the prospectus if you request it by calling Boustead Securities, LLC at 949.502.4408 or by email at offerings@boustead1828.com or standard mail at Boustead Securities, LLC, Attn: Equity Capital Markets, 6 Venture, Suite 395, Irvine, CA 92618, USA.

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 should not be 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. See offering documents for further risks and disclosures. Past performance is not indicative of future results. There is no guarantee that any specific outcome will be achieved. Investments may be speculative, illiquid and there is a risk of total loss.

FORM CRS/REG BI DISCLAIMER:

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DISCLOSURE

General securities market uncertainties resulting in economic considerations.

Recent unease regarding geo-political considerations and uncertain inflation has caused the United States and worldwide 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 the Company 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, it 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.

The Company may need additional financing to support our technology development and ongoing operations, pay our debts and maintain ownership of our intellectual properties.

It is currently operating at a loss and using substantial cash to fund our operation. It believes that its cash on hand will be sufficient to fund operations through September 30, 2024. It may need additional financing to implement its business plan and to service its ongoing operations, pay current debts (described below) and maintain ownership of its intellectual property. There can be no assurance that it will be able to secure any needed funding, or that if such funding is available, the terms or conditions would be acceptable. If it is unable to obtain additional financing when it is needed, it will need to restructure its operations and/or divest all or a portion of its business. The Company 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 its ability to take specific actions, such as incurring additional debt, and could increase its expenses and require that its assets secure such debt. Equity financing, if obtained, could result in significant dilution to its 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, it may be required to delay, scale back, eliminate the development of business opportunities and its operations and financial condition may be materially adversely affected.

The Company has a history of operating losses and there can be no assurance that we can achieve or maintain profitability.

It has experienced net losses since inception. As of September 30, 2023, it had an accumulated deficit of \$121,841,000 and net losses in the amount of \$15,289,000 and \$20,071,000 for the years ended September 30, 2023 and 2022, respectively. There can be no assurance that it will achieve or maintain profitability. If it achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair its ability to sustain operations and adversely affect the price of its common stock and its ability to raise capital. Its operating expenses may increase as it spends resources on growing its business, and if revenue does not correspondingly increase, its operating results and financial condition will suffer. Its businesses have produced minimal revenues and may not produce significant revenues in the near term, or at all, which would harm its ability to continue its operations or obtain additional financing and require it to reduce or discontinue its operations. You must consider the Company's business and prospects in light of the risks and difficulties it will encounter as a business with an early-stage technology in a new and rapidly evolving industry. It may not be able to successfully address these risks and difficulties, which could significantly harm its business, operating results and financial condition.

If the Company is unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities, it may not be able to successfully commercialize our technology.

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

It may not be able to enter into collaboration agreements on terms that are acceptable at all. In addition, even if it enters into such relationships, it may have limited or no control over the sales, marketing and distribution activities of these third parties. Its future revenues may depend heavily on the success of the efforts of these third parties. If it elects to establish a sales and marketing infrastructure, it may not realize a positive return on this investment. In addition, it 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 its efforts to commercialize technology without strategic partners or licensees include:

- its 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 it 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 its products can be sold and there is no assurance such approval will be granted.

The Company's technology is being designed to 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, it is exploring the use of its technology for certain medical diagnostic applications, with an initial focus on the monitoring of blood glucose. There is no assurance that it will be successful in developing glucose monitoring medical applications for its technology. If the Company is to be successful in developing glucose monitoring medical applications of its technology, prior clearance by the FDA and other governmental regulatory bodies will be required before the technology could be introduced into the marketplace. Its devices are being designed to leverage Machine Learning (ML) and Artificial Intelligence (AI) to process the massive data collected through the KnowU 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-DSP) 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. It 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 its products could prevent it from generating revenue from these products or achieving profitability.

Overview

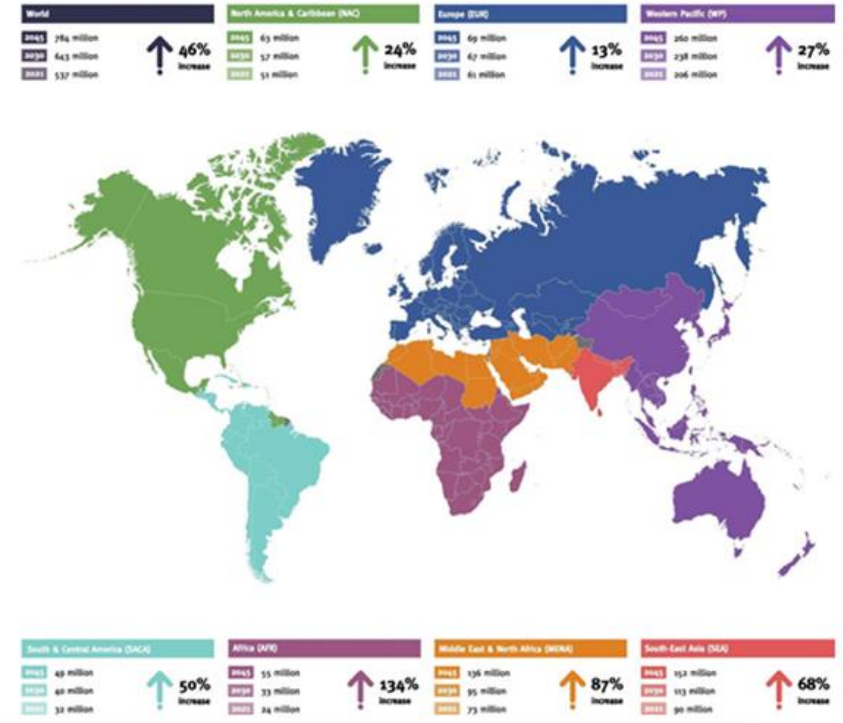
- The Problem: Diabetes is a Growing Global Problem Needing A Better Solution
- The Solution: A Medical Grade Non-Invasive Blood Glucose Monitor
- Competitive Landscape: Non-Invasive Challengers and Invasive Incumbents
- Know Labs Differentiation: How It Works and Why It Works
- Product Roadmap: The Next-Generation Blood Glucose Monitor
- Clinical Data: Meeting the FDA Requirements for Accuracy
- Path to Commercialization: 2024 and Beyond
- Intellectual Property: Global Leadership Across the Value Chain
- Summary: Why Know Labs?

The Problem: Diabetes is a Growing Global Problem Needing A Better Solution

Unmet Global Need: Diabetes is a Real World Problem of Growing Proportions

- CDC 1994: “The diabetes epidemic”
CDC 2022: “The diabetes pandemic”
- In the US, 1 in 9 adults have diabetes. In the rest of the world, that can reach 1 in 3.
- Diabetes reduces life expectancy 8 to 10 years. Comorbidities include cancer, heart disease, stroke, hypertension, etc.
- Worldwide - less than 1% CGM penetration; for the other 99%, daily finger sticks are the only other option or doing nothing at all.
- Non-invasive blood glucose monitoring is the next generation capable of reaching the world.

Diabetes around the world | 2021



Per International Diabetes Foundation, as of 2021. See Citation Slide, 1

The Solution: A Medical Grade Non-Invasive Blood Glucose Monitor

The Disruptive Next Generation of Non-Invasive Medical Diagnostics

Know Labs Global Mission

Know Labs is committed to making a difference in the lives of millions of people around the world by developing convenient, affordable non-invasive medical diagnostics solutions, starting with blood glucose monitoring.

Know Labs is developing a highly novel, patented non-invasive continuous glucose monitor (CGM) it believes will be the world's first FDA cleared medical device for non-invasive diabetes management.

Competitive Landscape: Non-Invasive Challengers and Invasive Incumbents

The Non-Invasive Race Is On

Bloomberg

Samsung explores development of non-invasive blood sugar monitoring

January 24, 2024

"If we can do continuous glucose, we're in a whole different ball game," Dr Pak, Samsung's mobile digital health chief, said during an interview. "I think that's where everyone is trying to get to. We're putting significant investment towards that."

He would not comment on a timeline for either feature, but said he hopes non-invasive glucose monitoring could come to the market in some form within five years (2029).

- Dr. Hon Pak, M.D.
Head of Digital Health
Samsung Electronics

Per Bloomberg Jan 2024. See Citation Slide, 2



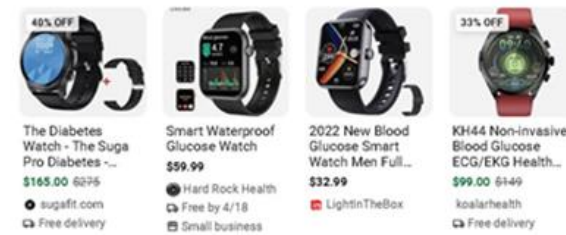
The Race Is Obscured By Pretenders

Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication

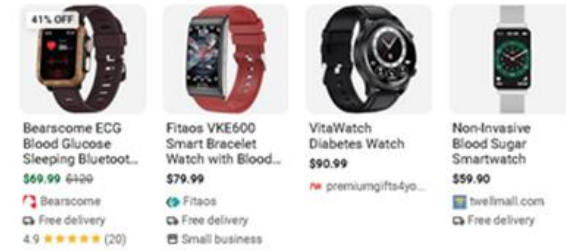
Date Issued: February 21, 2024

The U.S. Food and Drug Administration (FDA) is warning consumers, patients, caregivers, and health care providers of risks related to using smartwatches or smart rings that claim to measure blood glucose levels (blood sugar) without piercing the skin. These devices are different than smartwatch applications that display data from FDA-authorized blood glucose measuring devices that pierce the skin, like continuous glucose monitoring devices (CGMs). The FDA has not authorized, cleared, or approved any smartwatch or smart ring that is intended to measure or estimate blood glucose values on its own.

For people with diabetes, inaccurate blood glucose measurements can lead to errors in diabetes management, including taking the wrong dose of insulin, sulfonylureas, or other medications that can rapidly lower blood glucose. Taking too much of these medications can quickly lead to dangerously low glucose, leading to mental confusion, coma, or death within hours of the error.



48% OFF The Diabetes Watch - The Suga Pro Diabetes --- \$165.00 \$275 sugafit.com Free delivery	Smart Waterproof Glucose Watch \$59.99 Hard Rock Health Free by 4/18 Small business	2022 New Blood Glucose Smart Watch Men Full... \$32.99 LightinTheBox	33% OFF KH44 Non-Invasive Blood Glucose ECG/EKG Health... \$99.00 \$149 koalarhealth Free delivery
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41% OFF Bearscome ECG Blood Glucose Sleeping Bluetooth... \$69.99 \$100 Bearscome Free delivery 4.9 ★★★★★ (20)	Fitaos VKE600 Smart Bracelet Watch with Blood... \$79.99 Fitaos Free delivery Small business	VitaWatch Diabetes Watch \$90.99 premiumgifts4yo...	Non-Invasive Blood Sugar Smartwatch \$59.90 twelldmall.com Free delivery
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Blood pressure, Blood oxygen, Heart rate monitoring

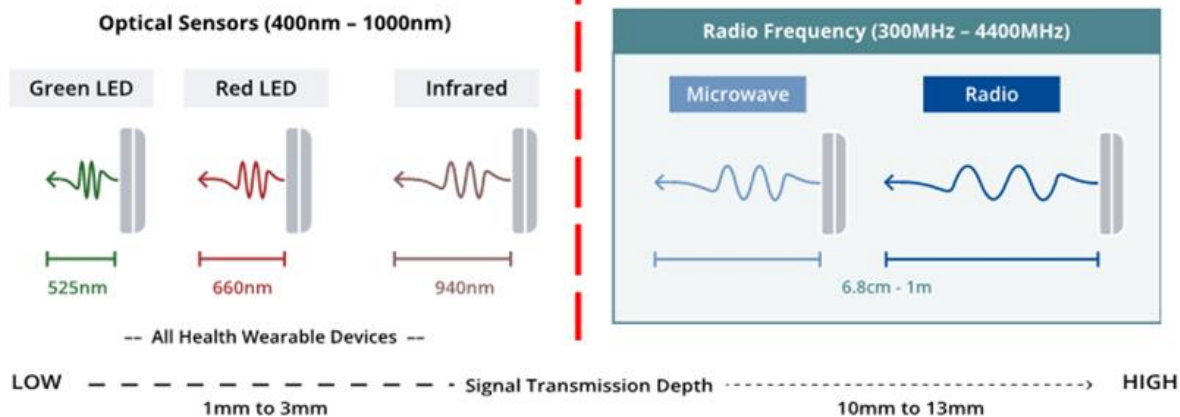
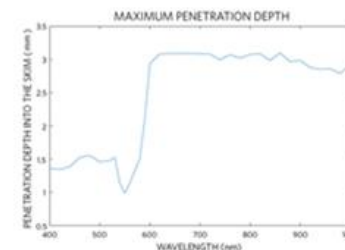
Use professional human body sensor chip to enhance test accuracy

Per FDA Feb 2024. See Citation Slide, 3

Why Optical Blood Glucose Sensors Don't Work And Know Labs Does

Samsung / Apple
785 nm

LIMITATIONS OF A \$18 BOM FOR 9 SENSORS



First Principles: RF Energy Overcomes the Limitations of Physics

Tunable RF wavelength 68 million to 1 billion nm versus fixed IR wavelength 1000 nm

RF Dielectric Spectroscopy sweeps entire tissue stack to a depth of 13 mm to collect high resolution voltage change data that fixed wavelength optical sensors are incapable of achieving.

The dielectric constant (relative permittivity) of glucose is 74.3 and decreases as the concentration of glucose increases.

Tunable Photonics, See Citation Slide 4 / ICNIRP, See Citation Slide 6

Invasive Glucose Measurement: Enzymes Have Dominated for Over 80 Years

- From urine test strips from the 1940s to finger stick strips from the 1980s to current CGMs from the 2000s, all glucose measurement modalities rely on enzymes because of their high specificity, albeit limiting their functionality to their single target analyte.
- Generation 0 Urine Strips: If blood glucose exceeds the kidneys ability to reabsorb glucose >180 mg/dL, then it's present in the urine (glucosuria).



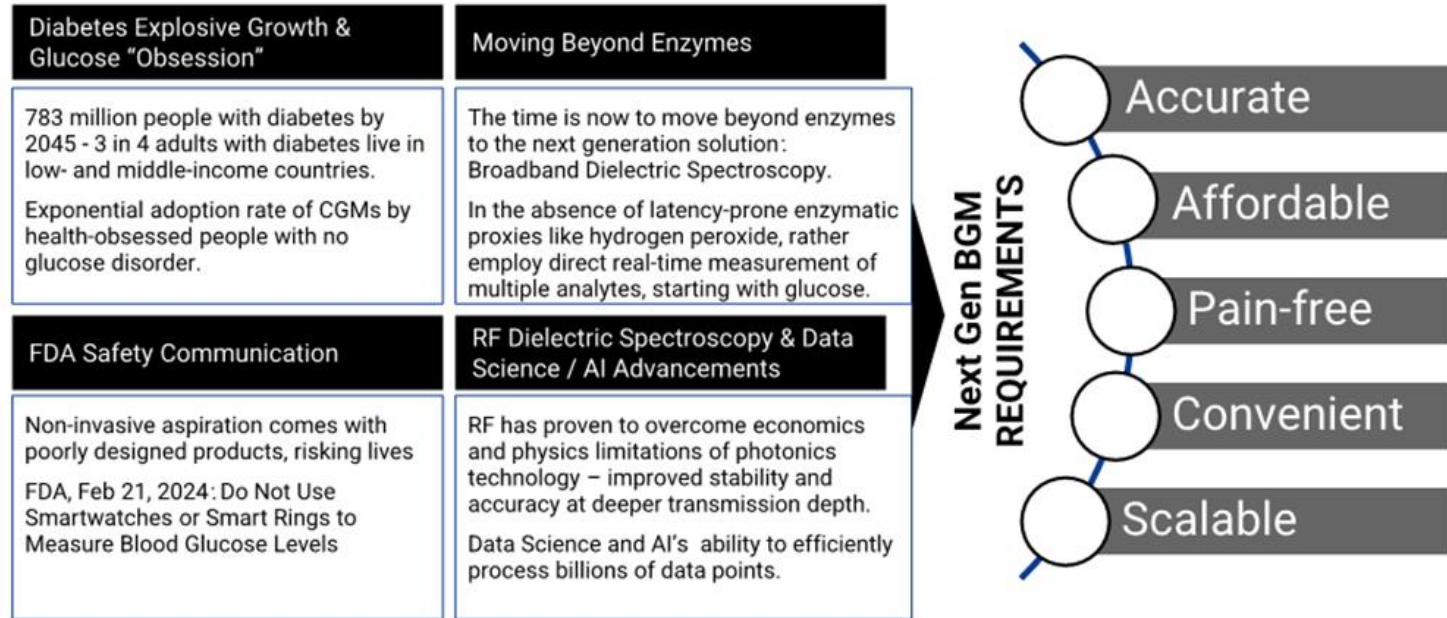
Introduced in the 1940s, detection of glucose by urine test strips is based on the enzymatic reaction of glucose oxidase, the same enzyme used in today's CGMs. This enzyme catalyzes the oxidation of glucose to form gluconic acid and hydrogen peroxide, again like today's CGMs. Results are visually color matched to a scale, rendering qualitative interpretation across a wide glycemic range (i.e. 300 to 1000). This approach is limited to detecting hyperglycemia and is not effective at detecting hypoglycemia.

Enzyme Testing for Glucose Measurement, see Citation Slide 7

Current Invasive BGMs are Good, but could be Much Better

	1 st Generation Finger Stick	2 nd Generation CGM	Key Pain Points
			<ul style="list-style-type: none"> • Inconsistent accuracy across hypo, normal and hyperglycemic ranges • High cost, limiting access to uninsured and emerging countries' populations • Invasive and inconvenient • High volume of plastic-based disposables (not environmentally friendly) • Not scalable, enzyme limited to one analyte monitoring • High failure rate and FDA MAUDE adverse event cases
Examples	Roche – Accu-chek. Ascensia – Contour Lifescan – OneTouch. One Drop Meter	Dexcom – G7 Medtronic – Guardian Abbott – Freestyle Libre 3	
FDA Cleared	Early 1980s	Mid 2000s	
Technology	Enzymatic Electrochemical: the enzyme on the strip, glucose dehydrogenase, converts glucose to gluconolactone. This creates an electrical current that serves as a proxy for glucose levels	Enzymatic Electrochemical: 5 mm microneedle coated with glucose oxidase oxidizes the glucose in the interstitial fluid, producing hydrogen peroxide and an electrical current proportional to glucose levels	
Use Interface	Invasive fingerstick 1-10 fingersticks/day	Invasive microneedle Continuous wear	
MARD	5% to 8%	8% to 10%	
Consumables	Single-use test strips and lancets	New sensor every 10 to 14 days	
Retail Cost	>\$1,500	\$2,500 to \$5,000	

Now is a Prime Moment for BGMs Disruption



Per International Diabetes Foundation, as of 2021 and FDA, 2024. See Citation Slide, 1 and 3

Meet the Next Generation of BGM: The KnowU™



-Dimensions (w x d x h) 47 x 76 x 20 mm
- Weight. 100 g

* Know Labs Goal. Best results to date achieved 11.1% MARD for known population
** Estimated annual retail cost based on current BGM

<10% MARD across all ranges *

No Needles | 100% Non-invasive

No Consumables | Rechargeable

Affordable | <\$1,000 annual retail cost**

Continuous Monitoring | Real-time Data

Wearable | Adhesive or Strap

RF Dielectric Spectroscopy

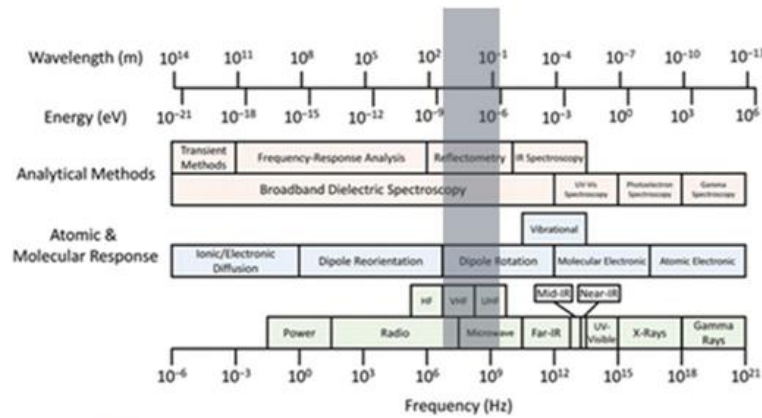
AI/ML-Powered Algorithms

100+ Potential Applications

Per Know Labs internal testing, as of June 2024

Know Labs Differentiation: How It Works and Why It Works

How It Works and Why It Works



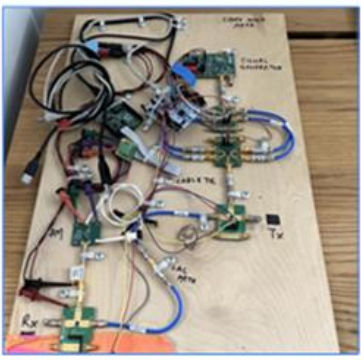
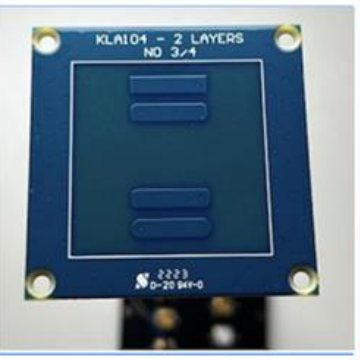


Where KnowU sits on the electromagnetic spectrum

Oxford Institute, See Citation Slide 5

- Optical sensors emit light energy which has a very limited ability to penetrate the human body (1 mm to 3 mm), therefore prone to reflection, absorption, back scattering and other forms of interference, rendering an inaccurate non-medical grade blood glucose signal.
- Current glucose monitors are invasive and rely on electrochemical enzymatic reactions from either capillary blood or interstitial fluid (5 mm) to generate an electrical current proportional to blood glucose; and therefore able to achieve medical grade accuracy readings with MARD readings of 5% to 8% for finger sticks to 8% to 10% for incumbent CGMs. While highly specific, enzymes are limited to a single analyte.
- The human body is comprised of polar (water soluble) and non-polar (non-water soluble) molecules which respond to the transmission of RF electromagnetic energy across many analytes in a defined manner.
- The KnowU detects glucose levels in real-time across the “tissue stack” (interstitial fluid, capillary blood, venous blood, cellular glucose) using non-invasive RF dielectric spectroscopy to a depth of 13 mm.
- KnowU activates the dielectric properties of glucose, a polar molecule in the body, and its ability to store electrical energy in an electric field (known as permittivity). Glucose has a distinctive conformational dipole rotation.
- Using time frequency sweeps, KnowU rapidly scans a large range of RF frequencies and records voltage values detected at each frequency to quantify real-time blood glucose continuously, with MARD readings approaching 10%. Know Labs plans to reach sub-10% MARD across mixed cohorts of hypoglycemic to hyperglycemic ranges.

Product Roadmap: The Next Generation Blood Glucose Monitor

KnowU Product Development Roadmap

2019: Proof-of-Concept	2021: Generation 0	2023: Generation 1	2024: KnowU™
			
<ul style="list-style-type: none"> • Exploratory design • Multiple components wired to each other • Signal testing purpose • 2' x 3' board 	<ul style="list-style-type: none"> • Miniaturized format • Wired connection to power source and data capture • Restricted to laboratory controlled environment 	<ul style="list-style-type: none"> • On-the-go form factor • Place your palm or arm for an on-demand, non-invasive blood glucose level • Computer mouse size 	<ul style="list-style-type: none"> • Wearable form factor • Continuous monitoring • 85% smaller and 75% lighter than previous Generation

KnowU Details: Wearable Form Factor



KnowU Product Specifications

- Wearable**
Adhesive, or strap for wrist or arm. Clip system allows for easy sensor attachment.
- Battery**
24-hour continuous use. Rechargeable.
- Algorithm**
Multiple algorithms in development. See Know Labs Scientific Validation mobile app page.
- Mobile app**
Designed to companion the KnowU CGM device. Enables advanced research.
- Data Storage**
256MB flash storage. 40 hours of offline research data.
- Connectivity**
BLE, WiFi, USB-C.
- Processor**
Ultra-low power consumption, onboard computer. Wi-Fi & BLE capabilities, built-in ML.
- Firmware**
Custom firmware supports the entire tech stack.



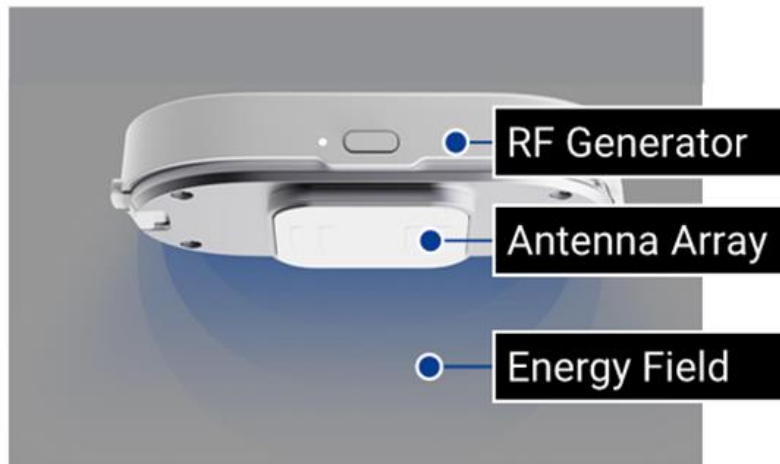
KnowU vs. Gen 1

85% smaller

75% lighter

RF Dielectric Sensor

IP-PROTECTED | INCLUDED IN THE KNOWU



Energy Field Dimensions at 2,500 MHz
- w x d x h: 2.54 x 2.00 x 1.27 cm
- 5.4 cm³ of 3D volumetric data

RF Generator enables frequency sweeps from 300 to 4,400 MHz, at various intervals, 1.5M data points collected per hour = >400 per second

Antenna Array that emits and captures radio wave signals in the microwave spectrum and generates an "Energy Field", collecting "volumetric data"

6 Key Parameters, customizable with each sweep: power, frequency range, frequency step, dwell time, and antenna permutations = >30,000 combinations

Per Know Labs internal testing, as of June 2024

KnowU App



DexCom App

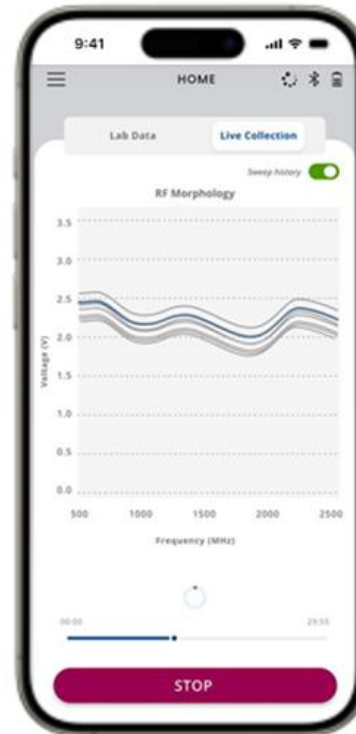


These images show an example of the Know Labs app screen as compared to the Dexcom app screen. The glucose values indicated on each app screen are examples only and not actual readings. The glucose readings are not being compared.

Opens Gateway to Future Analytes and App Subscription Model

Platform Technology Offers
More Functionality
And Opportunity
For Recurring Revenue
From Other Analytes
In the Future
(Ketones, Cortisol, Troponin,
Metabolized Drugs, etc.)

SaMD
Software-as-Medical-Device



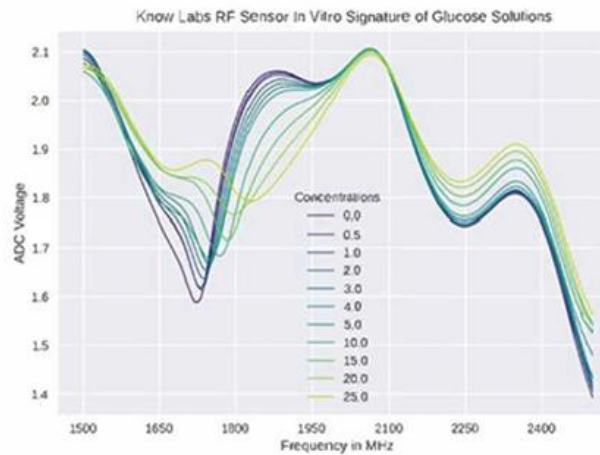
Our App Developer
SYNCR
MEDICAL

Clinical Data: Meeting the FDA Requirement for Accuracy

ACCURACY FROM IN VITRO TO IN VIVO GLUCOSE TESTING

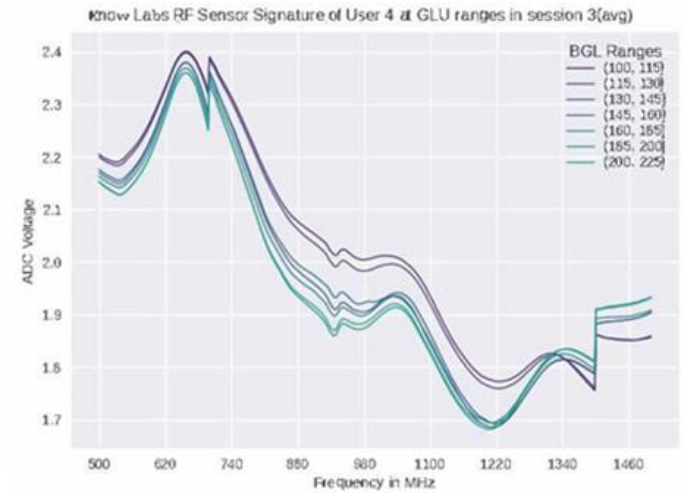
- **IN VITRO:** RF dielectric spectroscopy sensor can measure different concentrations of glucose in solution, where optical sensors cannot.
- **IN VIVO:** Non-invasive RF sensors based on dielectric permittivity can measure variance in blood glucose in BGL ranges.

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

Per PubMed May 2023, See Citation Slide 8

SCIENTIFIC VALIDATION: FY2023 – 2024: Sensors Journal, APS, AACE, ATTD



Detecting Unique Analyte-Specific Radio Frequency Spectral Responses in Liquid Solutions—Implications for Non-Invasive Physiologic Monitoring

Dominic Klyve ^{1,*}, James H. Anderson, Jr. ², George Lovette ³ and Vivend K. Somers ³

¹ Department of Mathematics, Central Washington University, Ellensburg, WA
² Know Labs Inc., Seattle, WA, 98101, USA, info@knowlabs.com
³ Mayo Clinic, Rochester, MN 55902, USA, benita.gongg@mayoclinic.org,
 * Correspondence: klyved@cwu.edu

Abstract: With rising healthcare costs and the rapid increase in remote care delivery, there is an increasing need for economical, accurate, a measure of blood analytes. Based on radio frequency identification (RF) technology (the Bio-RFID sensor) was developed to non-invasively capture data from individual radio frequencies, and convert those data into digital information and insights. Here, we describe groundbreaking use of Bio-RFID to accurately measure various concentrations of analytes in a variety of liquid solutions. For this assessment, varying concentrations of analytes in water, and (2) commercial blood in water were used in a double-blind trial design, as proxies for biochemical solutions in vivo. We were able to detect concentrations of 2000 parts per million (ppm), with a detectably smaller concentration differences.

METHOD

- In a series of 46 tests (92 samples), five participants placed sensors on the Bio-RFID sensor and consumed 33.3 grams of liquid D-glucose.
- We measured their BGC for three hours using the Dexcom G6 as a reference device, while logging the readings of the sensor.
- Data were collected on a continuous basis, using sweeps across the 500 MHz – 1500 MHz range at 0.1 MHz intervals, collecting values at 15000 frequencies per sweep.
- Using the data captured with the Bio-RFID sensor, we trained a NN model to predict BGC readings of the Dexcom G6 as a proxy for BGC.



Technical Feasibility of a Novel Sensor for Non-Invasive Blood Glucose Monitoring Compared to Dexcom G6[®]

Dominic Klyve¹, Ph.D., Barry Shelton¹, Ph.D., Carl Ward, Ph.D.¹, David Schwarz², James H. Anderson, Jr., M.D.³, Steve Kant³
¹Department of Mathematics, Central Washington University Ellensburg WA223, USA, klyved@cwu.edu * Know Labs, Inc., ²Edge Impulse, Inc.

BACKGROUND & AIM

For the over 327M people living with diabetes, current methods of testing blood glucose concentration (BGC) come with drawbacks, whether they use traditional blood draws and test strips or more modern continuous glucose monitors (CGMs): the pain of finger sticks or CGM probe insertion, the recurring cost of test strips or one-time use probes, and the environmental impact of both.

Know Labs has developed a novel electromagnetic platform technology – the Bio-RFID[®] platform – to non-invasively capture data from individual radio frequencies and convert those data into physiologically meaningful information and insights.

We investigated the technical feasibility for this new method to quantify blood glucose in vivo non-invasively using RF by means of training a neural network (NN) model to predict readings of the Dexcom G6 as a proxy for BGC.

METHOD

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- Using the data captured with the Bio-RFID sensor, we trained a NN model to predict BGC readings of the Dexcom G6 as a proxy for BGC.

RESULTS

In aggregate, across the five individual participants and 92 samples, we observed a mean absolute relative difference (MARD) of 28.6%, in accordance to FDA limits for accuracy for new blood glucose monitors a prediction is “within threshold” of the observed reference value if either: A) the prediction is within 15% of the reference value for blood sugars over 75 mg/dL, or B) the prediction is within 15 mg/dL for blood sugars below 75 mg/dL. **46% of the Bio-RFID predictions were within threshold.**



FIG. 1 Selected results predicted by the NN model, plotted with the Dexcom G6 readings across time.

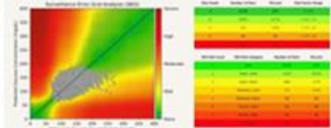


FIG. 2 Heat Map for prediction of the hold-out test dataset.

CONCLUSIONS

Though a clinically useful non-invasive BGC monitor should make 95% of predictions within threshold, we find these results encouraging given the relatively small size of the dataset. This study validated Bio-RFID as a viable platform to deliver reproducible results, and as infrastructure for future data collection. Because a truly non-invasive CGM would be a powerful tool in diagnosing, managing, and treating diabetes and pre-diabetes, more research is underway to continue refining and developing these algorithms.



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Detecting Unique Analyte-Specific Radio Frequency Spectral Responses in Liquid Solutions
 Implications for Non-Invasive Physiologic Monitoring

Benita Gongg, Ph.D.¹, Dominic Klyve, Ph.D.², George Lovette, Ph.D.³, Vivend K. Somers, Ph.D.³

BACKGROUND & AIMS

Know Labs has developed a novel electromagnetic platform technology – the Bio-RFID[®] platform – to non-invasively capture data from individual radio frequencies, and convert those data into physiologically meaningful information and insights. Here, we describe groundbreaking use of Bio-RFID to accurately measure various concentrations of analytes in a variety of liquid solutions. For this assessment, varying concentrations of analytes in water, and (2) commercial blood in water were used in a double-blind trial design, as proxies for biochemical solutions in vivo. We were able to detect concentrations of 2000 parts per million (ppm), with a detectably smaller concentration differences.

METHODS

In a series of 46 tests (92 samples), five participants placed sensors on the Bio-RFID sensor and consumed 33.3 grams of liquid D-glucose. We measured their BGC for three hours using the Dexcom G6 as a reference device, while logging the readings of the sensor. Data were collected on a continuous basis, using sweeps across the 500 MHz – 1500 MHz range at 0.1 MHz intervals, collecting values at 15000 frequencies per sweep. Using the data captured with the Bio-RFID sensor, we trained a NN model to predict BGC readings of the Dexcom G6 as a proxy for BGC.

RESULTS

In aggregate, across the five individual participants and 92 samples, we observed a mean absolute relative difference (MARD) of 28.6%, in accordance to FDA limits for accuracy for new blood glucose monitors a prediction is “within threshold” of the observed reference value if either: A) the prediction is within 15% of the reference value for blood sugars over 75 mg/dL, or B) the prediction is within 15 mg/dL for blood sugars below 75 mg/dL. **46% of the Bio-RFID predictions were within threshold.**

CONCLUSIONS

Though a clinically useful non-invasive BGC monitor should make 95% of predictions within threshold, we find these results encouraging given the relatively small size of the dataset. This study validated Bio-RFID as a viable platform to deliver reproducible results, and as infrastructure for future data collection. Because a truly non-invasive CGM would be a powerful tool in diagnosing, managing, and treating diabetes and pre-diabetes, more research is underway to continue refining and developing these algorithms.

CONCLUSION

The Bio-RFID technology accurately detects, measures, and quantifies specific analytes in liquid, while these findings have in vivo commercial applications, these proof-of-concept studies provide strong support for the application of the Bio-RFID for non-invasive bio-monitoring of physiologically and medically relevant analytes, such as glucose and alcohol, in the human body.

Per PubMed May 2023, See Citation Slide 8

ATTD 2024 Poster: ~11% MARD in Normal & Hyperglycemic Range

17th Advanced Technology & Treatment for Diabetes (ATTD) Conference, Florence, Italy March 6 – 9, 2024
 Presented by Dr. Virend Somers, M.D., Mayo Clinic

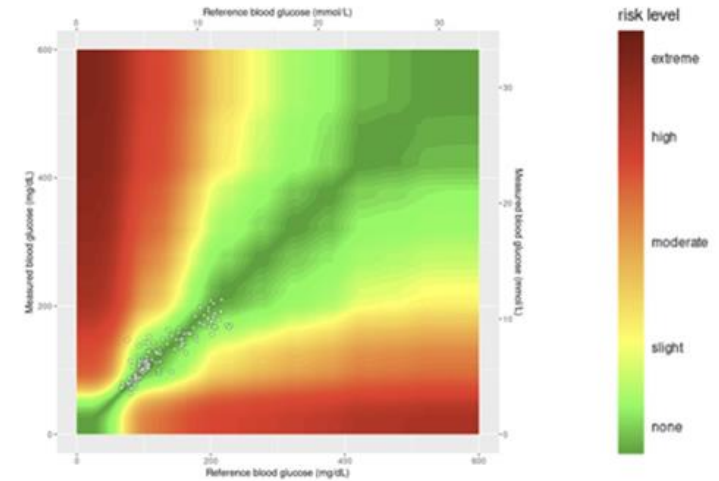
Non-Invasive Blood Glucose Monitoring in People with Diabetes Using an RF Sensor and Venous Blood Comparator

D. Klyve, J. Anderson, K. Currie, C. Ward, K. Pandya, V. Somers

- 30 participants with prediabetes and Type 2 diabetes
- Venous blood as a comparative reference
- 3-hour Glucose Tolerance Test (GTT)

Glucose Range (mg/dL)	n	MARD (%)	±15%	±20%
Hypoglycemic (<70)	4	9.5 ± 8.3	75.0 ± 4.2	100.0 ± 0.0
Normoglycemic (70-180)	99	11.0 ± 2.7	75.8 ± 0.8	83.8 ± 0.7
Hyperglycemic (>180)	27	11.5 ± 3.1	66.7 ± 1.8	85.2 ± 1.3
Total	130	11.1 ± 2.1	73.8 ± 0.8	84.6 ± 0.6

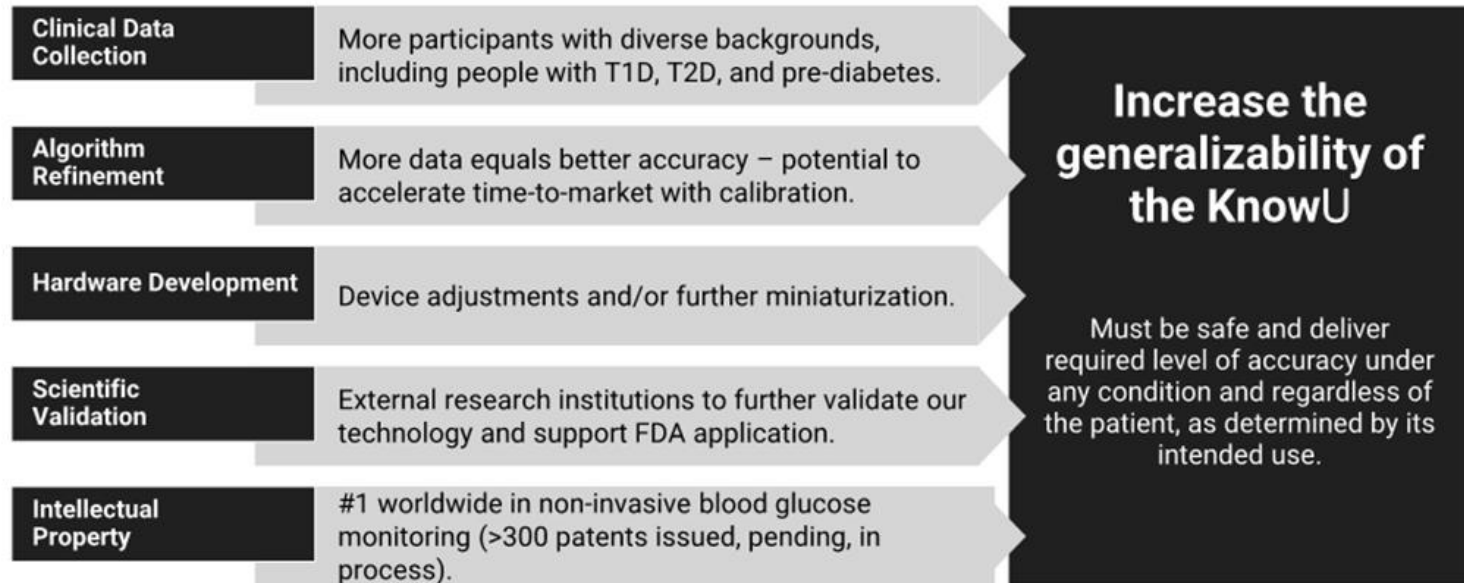
Per PubMed May 2023, See Citation Slide 8



100% of estimations in Risk Grades A and B (82.3% in A, 17.7% in B)

Path to Commercialization: 2024 and Beyond

2024 & Beyond

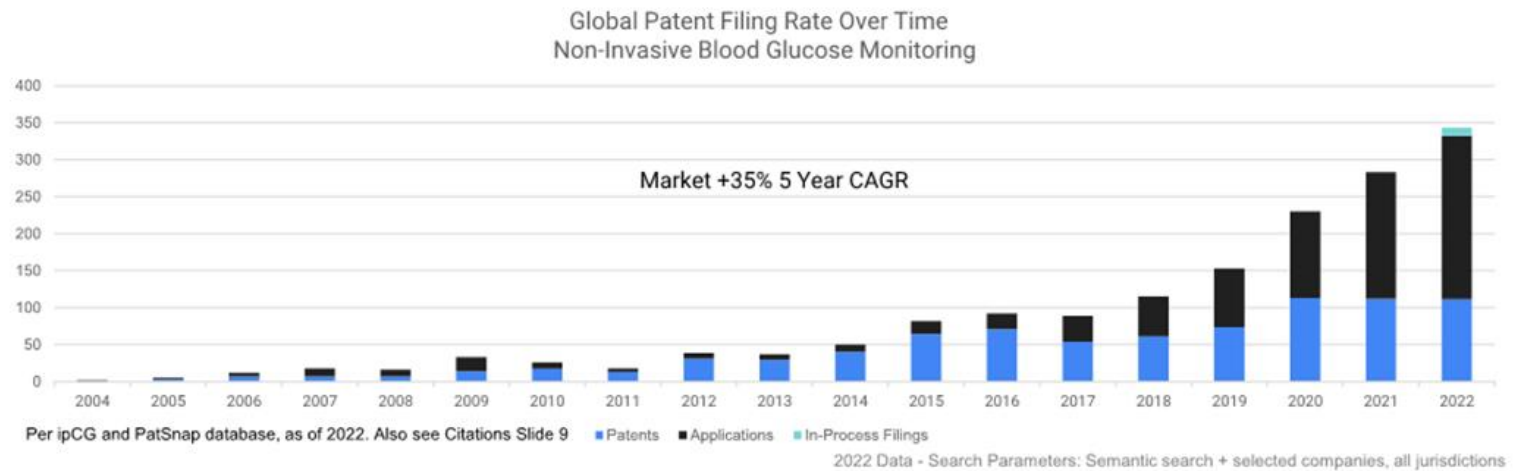


Intellectual Property: Global Leadership Across the Value Chain

KNOW LABS IP STORY: IP Market is Growing Rapidly in NI BGM

Yet, IP market is still early days with limited prior art challenges for Know Labs;
enables *headroom* to build a dominant IP portfolio

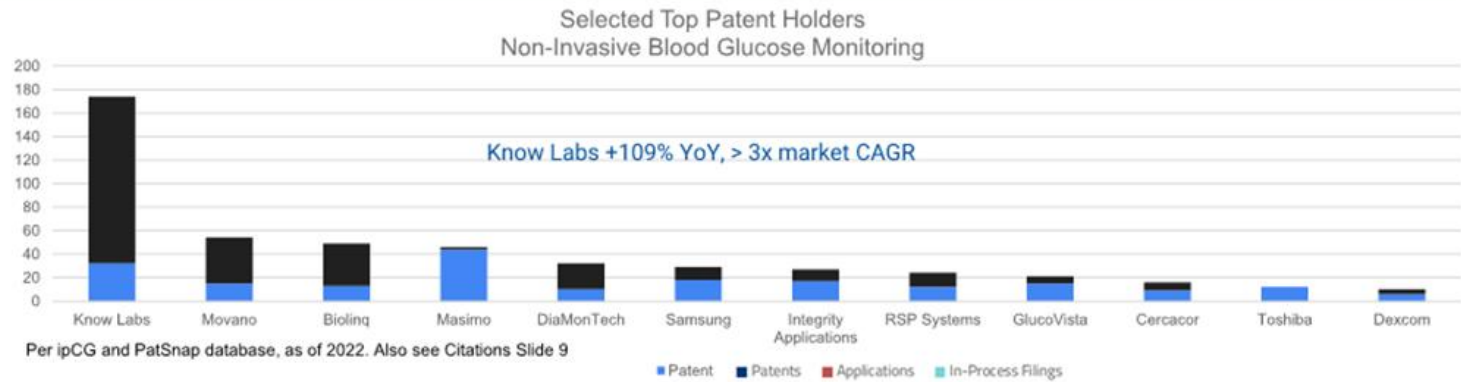
Know Labs is well positioned as an IP leader in a rapidly growing IP space



KNOW LABS: Extending Our IP Leadership Beyond Just Market Growth

Know Labs' accelerating IP growth reflects high rate of innovation, with significant and focused investment in strategic IP development

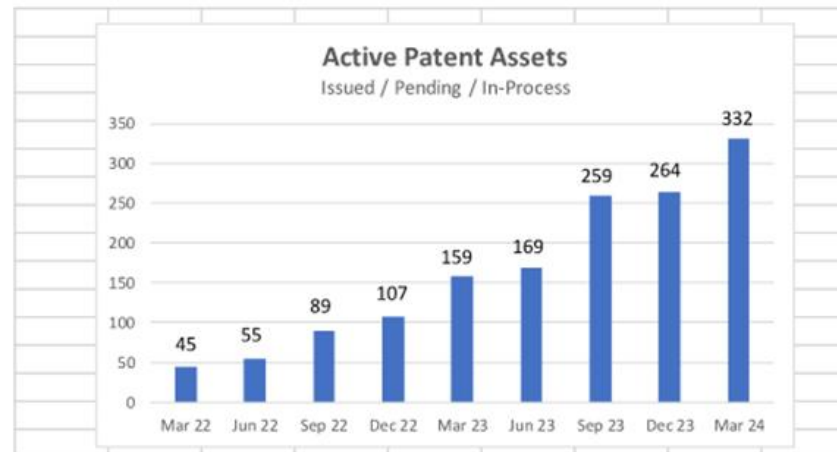
According to ipCG, Know Labs is the top worldwide IP holder in non-invasive blood glucose monitoring



2022 Data - Search Parameters: Semantic search + selected companies, all jurisdictions

IP Portfolio Overview: Global IP Leadership

Know Labs Patent Portfolio – March 2022 to March 2024



March 2022 to 2024: Our IP portfolio grew 7.4x

Per US Patent Office, as of June 2024, See Citation 9

- Strategic IP development program implemented in Q1 2023 with ipCapital Group
- 332 = 63 granted, 264 pending and 5 in-process
- 109% YoY growth, 3.1x IP market growth of ~35%
- Global coverage with patent assets in the US, PCT and 16 other jurisdictions worldwide:
 - US 214
 - PCT 38
 - EU 20
 - China 12
 - Japan 12
 - UK 10
 - HK 6
 - S Korea 6
 - Taiwan 5
 - Other* 9 (Australia, Canada, Indonesia, India, Brazil, Singapore, Pakistan, Saudi Arabia, UAE)

Why Know Labs?

Why Know Labs?

Emerging Leader	Global Innovator	IP Leadership	Medical Device	Platform Technology
<ul style="list-style-type: none"> • NYSE American IPO (Ticker: KNW) 9/15/2022 • Below the radar - current Form 13F Institutional Ownership <6%*. (25 institutions) • ~\$50M Market Cap versus >\$50B Market Cap for CGM incumbents, a factor of >1000x 	<ul style="list-style-type: none"> • Highly differentiated approach to glucose monitoring with high specificity & sensitivity • Combination of radio and microwave spectroscopy monitors high resolution analyte data in real-time • Unmet global market less than 1% served by CGM 	<ul style="list-style-type: none"> • More than 300 patents issued, pending and in-process filings worldwide create deep IP moat • Foundational patents cover more than 100 analytes • System-level interoperability to enable new hybrid architectures with CGM incumbents 	<ul style="list-style-type: none"> • Highly accurate medical device to serve the needs of hundreds of millions • Hundreds of tests proved that KnowU can measure blood glucose levels non-invasively • High level of accuracy • Current CGMs have 20 - 35% failure rates 	<ul style="list-style-type: none"> • Real-world commercialization opportunities across multiple industries • 100+ potential applications and use cases in medical diagnostics and beyond • F500-class development partners to bring to products to market
<p>* Form 13Fs as of 3/31/2024, See Citation Slide 10</p>				

Citations

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