

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 11, 2024

KNOW LABS, INC.

(Exact name of registrant as specified in its charter)

<u>Nevada</u> (State or other jurisdiction of incorporation)	<u>000-30262</u> (Commission File Number)	<u>90-0273142</u> (IRS Employer Identification No.)
<u>500 Union Street, Suite 810, Seattle, Washington</u> (Address of principal executive offices)		<u>98101</u> (Zip Code)

(206) 903-1351
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	KNW	NYSE American LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging Growth Company

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

Item 7.01 Regulation FD Disclosure.

On July 11, 2024, Know Labs, Inc. (the “Company”) issued a press release announcing interim results from its most recent clinical research study.

The information included in this Item 7.01 of this Current Report on Form 8-K, including the attached Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated July 11, 2024. Filed herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 11, 2024

KNOW LABS, INC.

/s/ Ronald P. Erickson

Name: Ronald P. Erickson

Title: Chief Executive Officer

KNOW LABS

Know Labs Publishes Clinical Results in Leading Diabetes Journal

Study demonstrates accuracy for a proof-of-concept non-invasive glycemic status screening device.

SEATTLE – July 11, 2024 – Know Labs, Inc. (NYSE American: KNW), a leading developer of non-invasive medical diagnostic technology, today announced the publication of its peer-reviewed study in *Diabetes Technology & Therapeutics Journal* titled, “A Glycemic Status Classification Model Using a Radiofrequency Noninvasive Blood Glucose Monitor.” *Diabetes Technology & Therapeutics* is a leading, peer-reviewed journal covering all aspects of diagnosing and managing diabetes with cutting-edge devices, drugs, drug delivery systems, and software.

The published clinical research results demonstrate that Know Labs’ proprietary non-invasive radiofrequency (RF) dielectric sensor and trade-secret machine learning (ML) algorithms correctly classified an individual’s glycemic status as hyperglycemic, normoglycemic, or hypoglycemic with 93.37% accuracy compared to venous blood glucose values—serving as an early proof-of-concept for a novel, non-invasive diabetes screening device.

Today, more than 500 million people worldwide are living with diabetes, with 75% residing in low and middle-income countries and an estimated 240 million people worldwide remaining undiagnosed. Expanding the potential application of the recently announced KnowU™ beyond non-invasive continuous blood glucose monitoring, the non-invasive screening device could support underserved global populations by facilitating early identification and intervention—potentially reducing diabetes-related hospitalizations and increasing access globally.

“Early diagnosis and intervention for diabetes are critical to both improving patient outcomes and enabling healthcare systems to allocate resources more economically and efficiently,” said Ron Erickson, CEO and Chairman at Know Labs. “This proof-of-concept for the use of our novel RF sensor as a glycemic status screening tool indicates the device’s potential to help funnel previously undiagnosed patients more effectively into the healthcare system.”

Study Design

The study included 31 participants aged 18-65 with prediabetes or Type 2 diabetes. Know Labs’ RF sensor continuously scanned participants’ forearms for up to two, three-hour sessions each during a 75g Oral Glucose Tolerance Test, and a third session in which water was given instead of liquid glucose to act as a control. Concurrently, venous blood draws were taken every five minutes and measured with an FDA-cleared glucose hospital meter system to create 2,637 paired observations. Data was preprocessed using smoothing techniques and an 80/20 split was performed to create model training and test datasets, respectively. Know Labs trained a Time Series Forest ML model to estimate reference venous blood glucose values on 80% of the data consisting of 2,109 paired RF device and venous blood glucose values randomly selected from the total dataset and then tested on the remaining, held-out 20% (528 paired values).

Results

The findings show that from the total test dataset of 528 paired values, the model correctly classified glycemic status 93.37% of the time as hyperglycemic, normoglycemic, or hypoglycemic. The model achieved sensitivities of 96.63% and 85.51% for normoglycemic and hyperglycemic classes, respectively. Specificities were 84.51% and 96.92%. More data is required in the hypoglycemic range to evaluate sensitivity and specificity in that glycemic class. Importantly, none of the hyperglycemic values were categorized as hypoglycemia, and none of the hypoglycemic values were categorized as hyperglycemia.

The results support the accuracy of Know Lab's proprietary non-invasive RF dielectric sensor and ML techniques for glycemic status classification. Further research is needed to enrich the dataset for categorical screening and improve the accuracy and sensitivity of each glycemic status.

Efforts led by President, International, Chris Somogyi, will aim to expand this application beyond proof-of-concept alongside potential strategic partners for a Rest of the World (RoW) product that exploits Know Labs' proprietary RF technology for use as a screening device. This will occur in parallel, as the Company maintains its core focus on bringing the first FDA-cleared non-invasive continuous glucose monitor to the marketplace.

For more information on Know Labs, visit www.knowlabs.co.

About Know Labs, Inc.

Know Labs, Inc. is a public company whose shares trade on the NYSE American Exchange under the stock symbol "KNW." The Company's platform technology uses spectroscopy to direct electromagnetic energy through a substance or material to capture a unique molecular signature. The technology can be integrated into a variety of wearable, mobile or bench-top form factors. This patented and patent-pending technology makes it possible to effectively identify and monitor analytes that could only previously be performed by invasive and/or expensive and time-consuming lab-based tests. The first application of the technology will be in a product marketed as a non-invasive glucose monitor. The device will provide the user with accessible and affordable real-time information on blood glucose levels. This product will require U.S. Food and Drug Administration clearance prior to its introduction to the market.

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Safe Harbor Statement

This release contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements appear in a number of places in this release and include all statements that are not statements of historical fact regarding the intent, belief or current expectations of Know Labs, Inc., its directors or its officers with respect to, among other things: (i) financing plans; (ii) trends affecting its financial condition or results of operations; (iii) growth strategy and operating strategy; and (iv) performance of products. You can identify these statements by the use of the words “may,” “will,” “could,” “should,” “would,” “plans,” “expects,” “anticipates,” “continue,” “estimate,” “project,” “intend,” “likely,” “forecast,” “probable,” “potential,” and similar expressions and variations thereof are intended to identify forward-looking statements. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond Know Labs, Inc.’s ability to control, and actual results may differ materially from those projected in the forward-looking statements as a result of various factors. These risks and uncertainties also include such additional risk factors as are discussed in the Company’s filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended September 30, 2023, Forms 10-Q and 8-K, and in other filings we make with the Securities and Exchange Commission from time to time. These documents are available on the SEC Filings section of the Investor Relations section of our website at www.knowlabs.co. The Company cautions readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. The Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made.

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