

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): May 30, 2023

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>
<u>Common Stock, par value \$0.001</u>	<u>KNW</u>	<u>NYSE American LLC</u>

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 May 30, 2023, Know Labs, Inc. (the “Company”) announced 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, demonstrating an overall Mean Absolute Relative Difference (MARD) of 12.9% – which is within the range of FDA-cleared blood glucose monitoring devices.

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 May 30, 2023. 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: May 30, 2023

KNOW LABS, INC.

/s/ Ronald P. Erickson

Name: Ronald P. Erickson

Title: Chief Executive Officer



Know Labs' Non-Invasive Glucose Monitoring Technology Shows Improved Accuracy

Latest study demonstrates a machine learning model improved Bio-RFID™ sensor's accuracy for predicting blood glucose, using the Dexcom G6® as reference device

SEATTLE – May 30, 2023 –Know Labs, Inc. (NYSE American: KNW) today announced 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, demonstrating an overall Mean Absolute Relative Difference (MARD) of 12.9% – which is within the range of FDA-cleared blood glucose monitoring devices. Bio-RFID is a novel technology platform that uses electromagnetic energy in the form of radio waves to non-invasively capture molecular signatures and convert them into meaningful information.

Like all previous Know Labs clinical studies, 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 proxy for the measurement of blood glucose. Unique from previous studies, Know Labs tested new data science techniques and trained a lightGBM model to predict blood glucose using 1,555 observations – or reference device values – from over 130 hours of data collection across five healthy participants. Using this model, 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 12.7% in the normoglycemic range and 14.0% in the hyperglycemic range.

“This is a transformational time for Know Labs. We are constantly uncovering new learnings in our research, and in this case found that the lightGBM model is well-suited for these early datasets given the amount of data available,” said Steve Kent, Chief Product Officer at Know Labs. “In our previous technical feasibility study we utilized a neural network, and as is best practice when developing algorithms, our data science team is constantly refining our machine learning models to understand and optimize system performance and accuracy. This positive development is another critical step in our data collection, algorithm refinement, and technical development.”

This study, which was peer-reviewed by Know Labs’ Scientific Advisory Board, builds upon recently released peer-reviewed research. In February, Know Labs published a proof-of-concept study that examined the efficacy of the Bio-RFID sensor using one participant, resulting in a MARD of 19.3%. Earlier this month, Know Labs also released study results validating the technical feasibility of Bio-RFID using a neural network (NN) model to predict readings of the Dexcom G6® as a proxy for blood glucose, which resulted in a MARD of 20.6%. The techniques used to analyze the data differed from previous analyses among the same (N=5) participant population, including: approach to feature reduction, stratification of the data by glycemic range and only from the arm corresponding to the reference device, and a different machine learning model. The improved accuracy as measured by a MARD of 12.9% achieved in this study is comparable to other independently validated MARD values reported for today’s FDA-cleared, commercially available CGM devices.

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“A MARD of 12.9% at this stage in our development is a truly remarkable feat. Our whole team is thrilled by these findings and the improved accuracy of our Bio-RFID technology as we continue to refine our approach,” said Ron Erickson, CEO and Chairman at Know Labs. “Our goal with these ongoing clinical studies is to develop large volumes of data to enable further model development, which is a critical step in our goal to bring the first FDA-cleared non-invasive glucose monitoring device to the market so that millions of people can manage their diabetes more efficiently.”

The full manuscript of this study will be submitted to a peer-review journal as Know Labs continues to prioritize external validation of the Bio-RFID technology. To view Know Labs’ growing body of peer-reviewed research, visit www.knowlabs.co/research-and-validation.

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 technology uses spectroscopy to direct electromagnetic energy through a substance or material to capture a unique molecular signature. The Company refers to its technology as Bio-RFID™. The Bio-RFID 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 our Bio-RFID technology will be in a product marketed as a non-invasive glucose monitor. It will provide the user with 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.

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, 2022, 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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