

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): **February 3, 2022**

KNOW LABS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State of other jurisdiction
of incorporation)

000-30262
(Commission
File Number)

90-0273142
(IRS Employer
Identification No.)

500 Union Street, Suite 810
Seattle, Washington 98101
(Address of principal executive office)

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

(Former name, former address and former fiscal year, 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 see General Instruction A.2. below):

- ☐ 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: None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01 Other Events.

On February 3, 2022, Know Labs, Inc. (OTCQB: KNWN), an emerging leader in non-invasive medical diagnostics, today announced it has received approval from an independent Institutional Review Board (IRB) for the protocol of its upcoming internal clinical trial. This brings the company one step closer to its FDA pre-submission meeting and to launching what it believes will be the first non-invasive glucose monitoring devices.

The clinical trial will be performed at Know Labs' new research and development laboratory in Seattle. Blood glucose readings for participants will be taken every five minutes with a Bio-RFID prototype, an Accu-Chek fingerstick device, and a continuous glucose monitor (CGM), such as Dexcom G6 or Abbott FreeStyle Libre, if the participant is already prescribed a CGM, over a period of three to five hours. During the test, participants will drink a glucola drink with 75 grams of sugar, which should change participants' blood glucose levels and provide Bio-RFID with the opportunity to accurately measure the changes.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

| Exhibit No. | Description |
|----------------------|---|
| 99.1 | Press release dated February 3, 2022. Filed herewith. |

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.

Registrant: **KNOW LABS, INC.**

By: /s/ Ronald P. Erickson

Ronald P. Erickson
Chairman of the Board

February 3, 2022



**Know Labs Receives IRB Approval to Begin Internal Clinical Trial of
Non-Invasive Glucose Monitoring Technology Bio-RFID™**

SEATTLE – February 3, 2022 – Know Labs, Inc. (OTCQB: KNWN), an emerging leader in non-invasive medical diagnostics, today announced it has received approval from an independent Institutional Review Board (IRB) for the protocol of its upcoming internal clinical trial. This brings the company one step closer to its FDA pre-submission meeting and to launching what it believes will be the first non-invasive glucose monitoring devices.

“Our team has been working diligently on getting ready for this trial,” said Phil Bosua, Know Labs CEO. “Testing our non-invasive technology with a larger population is a great opportunity to further validate the technology platform to identify and measure blood glucose levels accurately and non-invasively.”

The clinical trial will be performed at Know Labs’ new research and development laboratory in Seattle. Blood glucose readings for participants will be taken every five minutes with a Bio-RFID prototype, an Accu-Chek fingerstick device, and a continuous glucose monitor (CGM), such as Dexcom G6 or Abbott FreeStyle Libre, if the participant is already prescribed a CGM, over a period of three to five hours. During the test, participants will drink a glucola drink with 75 grams of sugar, which should change participants’ blood glucose levels and provide Bio-RFID with the opportunity to accurately measure the changes.

“In our most recent tests, Bio-RFID achieved a 5.8% MARD (mean absolute relative difference, a measure of glucose monitoring accuracy) when compared with other FDA-cleared devices,” Bosua said. “Those tests were performed with a much smaller population, so kicking-off a trial with 200 participants allows us to confirm Bio-RFID’s accuracy at a statistically significant level and also allows us to expand the conditions in which the tests are being performed.”

Know Labs expects to begin the trial in the coming weeks and is currently recruiting participants through the company’s website. Participants must be between 18 and 65 years of age and located in the Seattle area. A previous diagnosis of diabetes is not a requirement to enroll in the trial. For more information on the trial and Know Labs, visit www.knowlabs.co.

The IRB is an FDA registered constituted group that has been formally designated to review and monitor biomedical research involving human subjects.

Notice of Non-Affiliation and Disclaimer

Dexcom G6 is a registered trademark of Dexcom, Inc. Freestyle is a registered trademark of Abbott Laboratories, Inc. Accu-Chek is a registered trademark of Roche Diabetes Care, Inc. Know Labs is not affiliated, associated, authorized, endorsed by, or in any way officially connected with Dexcom, Abbott Laboratories or Roche Diabetes Care, or any of its subsidiaries or its affiliates.

About Know Labs, Inc.

Know Labs, Inc. is a public company whose shares trade under the stock symbol “KNWN.” 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 conduct analyses 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 glucose monitor. It will provide the user with real-time information on their blood glucose levels. This product will require U.S. Food and Drug Administration approval 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, 2020, 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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