

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): March 8, 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 March 8, 2022, Know Labs, Inc. a Nevada corporation (the “Company”), announced the Company’s outlook for 2022 and outlined preparations for a pre-submission meeting with the FDA. Know Labs is currently conducting an internal clinical trial of Bio-RFID™, its proprietary technology that has the potential to transform non-invasive medical diagnostics. Additionally, Know Labs plans to partner with a leading medical research institution to secure institutional validation for Bio-RFID with human subjects, which will help the company further demonstrate its technology and collect additional data for a pre-submission meeting with the FDA. In parallel to these activities, Know Labs will be completing the working prototype of its first product, the KnowU™ non-invasive glucose monitor. This unit and subsequent devices will be manufactured by the company’s manufacturing partner, Racer Technologies. As Know Labs prepares for FDA clinical trials, the company has selected the regulatory pathway it intends to pursue and present to the FDA in a pre-submission meeting.

To support its plan for 2022, Know Labs will make several strategic hires on its research and development, product development, corporate development, and regulatory teams. While the company will not require additional funding this year, it continues to work toward an uplist to a major national exchange, which could become a source of additional capital.

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
<u>99.1</u>	<u>Press release dated March 8, 2022. Filed herewith.</u>

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.**

Date: March 8, 2022

By: /s/ Ronald P. Erickson

Ronald P. Erickson
Chairman of the Board



Know Labs Provides 2022 Outlook, Outlines Preparations for Pre-Submission Meeting with FDA

SEATTLE – March 8, 2022 – Know Labs, Inc. (OTCQB: KNWN), an emerging leader in non-invasive medical diagnostics, today provided an update on its outlook for 2022, as the company executes its plan to bring the first FDA-cleared non-invasive glucose monitoring devices to market.

Know Labs is currently conducting an internal clinical trial of Bio-RFIDTM, its proprietary technology that has the potential to transform non-invasive medical diagnostics. Bio-RFID uses patented radio and microwave frequency spectroscopy to non-invasively detect and measure the presence of analytes, such as glucose, in the human body. The 200-person trial, approved earlier this year by an independent Institutional Review Board (IRB), offers an opportunity to further demonstrate Bio-RFID's accuracy in a large population. Bio-RFID has delivered high levels of accuracy and a Mean Absolute Relative Difference (MARD) under 6% when compared with other FDA-cleared glucose monitoring devices in internal tests with a smaller population size. To learn more about how Bio-RFID works and its potential applications, view this video.

Additionally, Know Labs plans to partner with a leading medical research institution to secure institutional validation for Bio-RFID with human subjects, which will help the company further demonstrate its technology and collect additional data for a pre-submission meeting with the FDA.

"Further refining our algorithm internally and validating our non-invasive technology with renowned medical institutions are important milestones for us, as we advance toward our FDA pre-submission meeting," said Phil Bosua, Know Labs CEO. "Right now, we're focused on completing our internal trial. We've had an outstanding response to the trials, with more people applying to participate than we can accommodate."

In parallel to these activities, Know Labs will be completing the working prototype of its first product, the KnowUTM non-invasive glucose monitor. This unit and subsequent devices will be manufactured by the company's manufacturing partner, Racer Technologies, valued manufacturer for many of the world's leading producers of FDA-cleared medical devices and wearable products.

As Know Labs prepares for FDA clinical trials, the company has selected the regulatory pathway it intends to pursue and present to the FDA in a pre-submission meeting. Some adjustments to the regulatory strategy may be required when the activities above are completed.

“New data from the CDC shows that 133 million Americans are living with diabetes or prediabetes, about one-third of the U.S. population,” said Ron Erickson, Know Labs Founder and Chairman. “Bio-RFID represents a significant breakthrough that can make a meaningful difference in human health and wellness, with the potential to revolutionize care for people with diabetes and pre-diabetes.”

Know Labs believes it will be the first company to bring an FDA-cleared non-invasive glucose monitoring device to market. While focusing on this priority, the company will explore additional applications of its non-invasive technology for detection of other analytes, such as ketones (fatty acids produced by the liver). Therefore, in addition to assisting patients with diabetes, Bio-RFID has the potential to lead to the early detection of many other disease states, such as heart disease and cancer.

According to independent research conducted by PatSnap, a leading patent intelligence company, Know Labs ranks No. 1 in patents covering Radio and Microwave Spectroscopy for Non-Invasive Continuous Glucose Monitoring (CGM) among leading global companies. Know Labs currently has a total of 30 patents granted and 48 patents pending and continues to aggressively expand its Bio-RFID patent portfolio as it pursues strategic value creation for its stakeholders.

In late 2021 Know Labs reported revenue of approximately \$4.2 million from the sale of non-fungible tokens (NFTs), created using its proprietary AI engine. The company will continue to utilize and seek to monetize its artificial intelligence, machine learning, and proprietary algorithm via its new subsidiary, AI Mind Inc. (AIM), with proceeds directed toward development of its non-invasive glucose monitoring technology.

To support its plan for 2022, Know Labs will make several strategic hires on its research and development, product development, corporate development, and regulatory teams. While the company will not require additional funding this year, it continues to work toward an uplist to a major national exchange, which could become a source of additional capital. Updates will be provided throughout the year and at its annual shareholder meeting, which the company expects to hold in the last quarter of 2022.

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

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 identify and monitor 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.

Know Labs, Inc. Contact:

Jordyn Hujar
jordyn@knowlabs.co
Ph. (206) 629-6414

Linhart PR for Know Labs Media Inquiries:

Kelly Brown
kbrown@linhartpr.com
Ph. (303) 951-2552

