

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): January 4, 2023

KNOW LABS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|---|---|
| Nevada (State or other jurisdiction of incorporation) | 001-37479 (Commission File Number) | 90-0273142 (IRS Employer Identification No.) |
| 500 Union Street, Suite 810, Seattle, Washington (Address of principal executive offices) | | 98101 (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:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--|--------------------------|--|
| 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 8.01 Other Events.

On January 4, 2023, Know Labs, Inc. (the "Company") published a press release disclosing details on a new foundational patent granted by the United States Patent and Trademark Office. U.S. Patent No. 11,529,077, titled High Performance Glucose Sensor. This patent equates the Company's Bio-RFID™ diagnostic technology to the current reference standard for glucose monitoring, widely used by diabetes researchers, hospital labs and glucometer manufacturers, and establishes a specific, superior benchmark range of clinical accuracy, known as MARD, for the Bio-RFID diagnostic platform.

The new patent extends the Know Labs IP portfolio to nearly 90 patents issued and pending, reinforcing the Company's position as a top worldwide IP holder in non-invasive blood glucose monitoring.

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.

(d) Exhibits

| Exhibit No. | Description of Exhibit |
|--------------------|---|
| 99.1 | Press Release dated January 4, 2023 - Filed herewith. |

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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: January 4, 2023

KNOW LABS, INC.

/s/ Ronald P. Erickson

Name: Ronald P. Erickson

Title: Chairman of the Board

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Know Labs, Inc. Expands IP Leadership in Non-Invasive Diagnostics with New High Performance Glucose Sensor Patent

SEATTLE – Jan 4, 2023 – Know Labs, Inc. (NYSE American: KNW), an emerging developer of non-invasive medical diagnostic technology, today announced it has been granted a new foundational patent that equates the company's Bio-RFID™ diagnostic technology to a current reference standard for glucose monitoring, widely used by diabetes researchers, hospital labs and glucose meter manufacturers, and establishes a specific, superior benchmark range of clinical accuracy, known as the MARD or Mean Absolute Relative Difference.

The new patent extends the Know Labs IP portfolio to nearly 90 patents issued and pending, reinforcing the company's position as the top worldwide IP holder in non-invasive blood glucose monitoring.

"Intellectual property development is a critical pillar of our success," said Ron Erickson, Know Labs Founder and Chairman. "We make significant investments in the strategic development of our IP Portfolio, which creates long-term value for our shareholders, improves our competitive position and accelerates our efforts to bring the first FDA-cleared, truly non-invasive glucose monitoring device to the market."

U.S. Patent No. 11,529,077, titled "High Performance Glucose Sensor," was just issued by the United States Patent and Trademark Office. This patent explicitly designates a MARD range of 5.0% to 9.9% for Know Lab's non-invasive diagnostics technology platform. MARD is an industry and FDA-accepted benchmark of clinical accuracy. The range patented for Know Labs' Bio-RFID platform is equal to or superior to the MARD readings of any FDA-cleared blood glucose monitoring products, highlighting its importance for Know Labs' future and its already robust IP Portfolio.

Know Labs Bio-RFID technology approaches blood glucose reading very differently than FDA-cleared devices currently available on the market. Radio frequency spectroscopy, enhanced by time-frequency synchronization and decoupled antenna designs, allows the Bio-RFID technology to collect a massive amount of data signals across real time glucose concentrations in the interstitial fluid, capillary and venous blood, and cellular tissue. Based on internal estimates, at 16mW at 2.5 GHz, Know Labs' sensor penetrates to an average 0.5 inches. In contrast, current micro-filaments used by minimally invasive devices, such as Dexcom® G6® and G7® and Abbott FreeStyle Libre® systems are limited to readings of only the interstitial fluid typically within 0.2 inches of the skin surface.

The patent also states that Know Labs' non-invasive diagnostic technology could become the new reference standard for glucose testing. The current "gold standard," the YSI™ Glucose Analyzer, measures only capillary blood. "The high accuracy of the [Know Labs] non-invasive glucose sensor described herein, when compared to lower accuracy glucose sensors such as minimally invasive CGMs and fingerstick glucose sensors, means that the [Know Labs] non-invasive glucose sensor can be used as a standard or reference sensor against which the accuracy of other glucose sensors are gauged. In one embodiment, readings from the non-invasive glucose sensor described herein can be used in place of readings obtained by a YSI glucose analyzer."

"We believe this is the first and only patent granted with a MARD range in its claims," Erickson said. "This is a significant milestone for Know Labs and for the non-invasive glucose monitoring industry, as it sets a new benchmark for MARD among all glucose sensors, invasive or not. We remain highly confident in our plans as we continue executing toward the

FDA clearance process. To build something that has never been done before, we need to approach the problem from a different angle. This patent shows we are doing that and validates that we are on the right track. There is more to be done. We believe our technology platform will transform the medical diagnostics industry and significantly improve the lives of millions of people worldwide.”

Know Labs will continue to provide updates on its intellectual property portfolio as patents are issued, along with progress toward clinical trials and FDA clearance of its non-invasive glucose monitoring devices. Know Labs' Technology is in development. Internal testing has demonstrated that Bio-RFID can deliver a MARD under 10%. The Company continues to test and refine Bio-RFID's hardware and algorithms in preparation for the FDA clearance process. There is no assurance Bio-RFID development and clearance will have a successful outcome. For more information on Know Labs, visit knowlabs.co.

Notice of Non-Affiliation and Disclaimer

Dexcom G6® and Dexcom G7® are registered trademarks of Dexcom, Inc. FreeStyle® is a registered trademark of Abbott Laboratories, Inc. YSI Glucose Analyzer® is a registered trademark of YSI Inc./Xylem Inc. Know Labs is not affiliated, associated, authorized, endorsed by, or in any way officially connected with Dexcom, Abbott Laboratories or YSI, or any of their subsidiaries or affiliates.

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.

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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, 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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