

**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): **December 18, 2024**

INTELLIGENT BIO SOLUTIONS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

001-39825
(Commission File Number)

82-1512711
(IRS employer identification no.)

135 West, 41st Street, 5th Floor
New York, NY 10036
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(646) 828-8258**

N/A
(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, \$0.01 par value	INBS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 December 18, 2024, Intelligent Bio Solutions Inc. (the “Company”) issued a press release (the “Press Release”) announcing the submission of its 510(k) premarket notification to the US Food and Drug Administration (FDA) for clearance following FDA review of its Intelligent Fingerprinting Drug Screening System. A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The foregoing disclosure is qualified in its entirety by the full text of the Press Release.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for the purpose of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

No.	Description
99.1	Press release dated December 18, 2024
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: December 18, 2024

INTELLIGENT BIO SOLUTIONS INC.

By: /s/ Spiro Sakiris

Name: Spiro Sakiris

Title: Chief Financial Officer

Intelligent Bio Solutions Announces 510(k) Submission to US FDA for Fingerprint Sweat-Based Drug Screening Technology

NEW YORK, December 18, 2024 – Intelligent Bio Solutions Inc. (Nasdaq: INBS) (“INBS” or the “Company”), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced the submission of its 510(k) premarket notification to the US Food and Drug Administration (FDA) for clearance following FDA review of its Intelligent Fingerprinting Drug Screening System (the “System”), an innovative, rapid and pain-free method for drug screening. The submission represents a critical milestone on the Company’s path to realizing its goal of entering the US market with its drug testing solution in 2025.

The Company’s 510(k) submission included performance data and validation studies, including a method comparison study that demonstrated the System’s 94.1% accuracy and a Pharmacokinetic (PK) study that showed fingerprint sweat provides a reliable sample matrix for drug detection, with quantitative PK data closely aligned to blood, based on statistical comparisons made at the 95% confidence level. These findings highlight the System’s accuracy, reliability, and usability, demonstrating its capacity to meet the growing demand for efficient, non-invasive testing solutions in the US market.

With existing adoption in international markets, the System has already demonstrated its value in delivering substantial cost savings, operational efficiencies, and rapid results with minimal disruption. Entry into the US, one of the largest drug screening markets globally, will support INBS’ ongoing global expansion, presenting opportunities for revenue growth, market share acquisition, and strategic partnerships.

The System’s accuracy and non-invasive nature position it to become a disruptive technology in safety-critical industries such as construction, mining, and transportation. Additionally, its application in the law enforcement, drug rehabilitation, and forensic sectors offers diverse revenue streams. Expansion into the US would strengthen the Company’s financial performance and enhance its position as a leader in pain-free testing solutions.

“The submission of our 510(k) application to the FDA is an impactful moment for all of us at Intelligent Bio Solutions, who have worked with perseverance and an intense focus to deliver our 510(k) package on time,” said Harry Simeonidis, President and CEO at INBS. “Our team showed agility and resourcefulness, working with our clinical research partners to execute our clinical study plan and analyze the data. We are excited about our planned entry into the US market, the opportunities for growth, and the transformational impact that we believe we will have in the drug screening market with our innovative technology.”

The Intelligent Fingerprinting Drug Screening System is designed to detect drugs of abuse through sweat collected from the fingertips and provide results within ten minutes. This non-invasive, hygienic, and easy-to-administer test is particularly beneficial in safety-critical industries such as construction, transportation, mining, and logistics. The System has broader applicability across the law enforcement, drug rehabilitation, and forensic sectors, highlighting its vast market potential.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering innovative, rapid, non-invasive testing solutions. The Company believes that its Intelligent Fingerprinting Drug Screening System will revolutionize portable testing through fingerprint sweat analysis, which has the potential for broader applications in additional fields. Designed as a hygienic and cost-effective system, the test screens for the recent use of drugs commonly found in the workplace, including opiates, cocaine, methamphetamine, and cannabis. With sample collection in seconds and results in under ten minutes, this technology would be a valuable tool for employers in safety-critical industries. The Company's current customer segments outside the US include construction, manufacturing and engineering, transport and logistics firms, drug treatment organizations, and coroners.

For more information, visit: <http://www.ibs.inc/>

Forward-Looking Statements:

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Intelligent Bio Solutions Inc. has attempted to identify forward-looking statements by terminology, including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, included in Intelligent Bio Solutions' public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. Intelligent Bio Solutions undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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