

**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): **June 28, 2023**

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.)

142 West, 57th Street, 11th Floor
New York, NY 10019
(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 June 28, 2023, Intelligent Bio Solutions Inc. (the “Company”) issued a press release (the “Press Release”) announcing that the Company had received guidance from the U.S. Food and Drug Administration on a regulatory pathway for expansion into the United States for its Intelligent Fingerprinting Drug Screening Cartridge and that the Company intends to submit 510(k) pre-market notification to the FDA

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 disclosed under Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press Release, dated June 28, 2023.
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: June 30, 2023

INTELLIGENT BIO SOLUTIONS INC.

By: /s/ Spiro Sakiris

Name: Spiro Sakiris

Title: Chief Financial Officer



Intelligent Bio Solutions Receives Guidance from U.S. FDA on a Regulatory Pathway for Expansion into the United States for its Intelligent Fingerprinting Drug Screening Cartridge

- Company intends to submit 510(k) pre-market notification to the FDA -

NEW YORK, June 28, 2023 — Intelligent Bio Solutions Inc. (Nasdaq: INBS) (“INBS” or the “Company”), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced it has received guidance from the U.S. Food and Drug Administration (the “FDA”) regarding the regulatory classification of its Intelligent Fingerprinting Drug Screening Cartridge. The FDA has provisionally determined that the cartridge falls within 21 CFR 862.3650, Opiate Test System, a Class II type device that requires the submission of a pre-market notification 510(k) and the FDA’s clearance prior to marketing. The preliminary assessment, in response to the Company’s March 2023 513(g) request for product classification, provides a clear regulatory pathway for INBS as part of the Company’s expansion strategy into the United States. The Company intends to submit a 510(k) pre-market notification for its proprietary Intelligent Fingerprinting Drug Screening Cartridge.

“We are pleased to receive the FDA’s preliminary assessment for our Intelligent Fingerprinting Drug Screening Cartridge, which is a key step in our expansion into the U.S. market,” said Harry Simeonidis, President and CEO of Intelligent Bio Solutions. “With its rapid collection time and portability, we believe our intelligent drug screening technology will redefine how U.S. workplaces approach testing by setting a new standard for drug testing procedures that prioritizes the dignity of employees while simultaneously enhancing operational efficiency for employers.”

The Intelligent Fingerprinting Drug Screening System is designed to detect the presence of specific drugs and/or their metabolites from fingerprint sweat. The system features a small, tamper-evident drug screening cartridge onto which ten fingerprint sweat samples are collected in less than a minute. The tamper-proof cartridges are designed to screen for multiple drug groups simultaneously, including combinations of opioids, cocaine, methamphetamines, benzodiazepines, cannabis, methadone, and buprenorphine, in an approach that offers a dignified, non-invasive, and rapid drug screening solution. The application of the technology in maintaining workplace safety has garnered positive feedback from the Company’s growing customer base of over 350 clients in other countries, successfully deterring substance abuse at work and ensuring employee well-being and compliance with health and safety policies.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (the “Company”) (Nasdaq: INBS) is a medical technology company delivering intelligent, 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. This hygienic, and cost-effective system is designed to screen for recent use of drugs commonly found in the workplace, including opioids, 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. Additionally, the Company’s biosensor platform has the potential to test for up to 130 indications, ranging from glucose to immunological conditions and communicable diseases. The Company’s current customer segments 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 drug and diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals (including from the FDA), 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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