

**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): **September 27, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 September 27, 2023, Intelligent Bio Solutions Inc. (the “Company”) issued a press release (the “Press Release”) announcing that the Company’s Intelligent Fingerprinting Drug Screening business had obtained recertification for the latest ISO 13485: 2016 harmonized quality management system standard for the medical device industry.

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 September 27, 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: September 27, 2023

INTELLIGENT BIO SOLUTIONS INC.

By: /s/ Spiro Sakiris

Name: Spiro Sakiris

Title: Chief Financial Officer



**Intelligent Bio Solutions Obtains ISO Recertification
for its Intelligent Fingerprinting Drug Screening Business**

International certification adds to Quality Management Systems credentials for the medical device industry and supports expansion plans into North America and Asia Pacific regions

NEW YORK, September 27, 2023 — Intelligent Bio Solutions Inc. (Nasdaq: INBS) (“INBS” or the “Company”), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced that its Intelligent Fingerprinting Drug Screening business has obtained recertification for the latest ISO 13485: 2016 harmonized quality management system standard for the medical device industry. The recertification is effective October 14, 2023, and will be valid for three years.

ISO 13485:2016 is the international standard for medical devices quality management system certification and is a requirement for medical device manufacturers operating across key regions, including the USA, Canada, Europe, Japan, Singapore, Malaysia and Saudi Arabia. Last year the US Food and Drug Administration published a proposed rule to harmonize its medical device quality management system, 21 CFR Part 820, to the ISO 13485 QMS standard.

“Receiving ISO 13485: 2016 certification confirms that our research and development, manufacturing facilities and operations for our drug screening products conform with the highest quality management system requirements for our target markets,” said Harry Simeonidis, President and Chief Executive Officer of Intelligent Bio Solutions. “We are currently focused on driving sales growth for our Intelligent Fingerprinting Drug Screening System across Europe and Australia. In the coming months, we plan to extend our sales efforts into other countries throughout the Asia Pacific region. Given this planned expansion, it is essential we meet the most stringent quality criteria recognized globally.”

The ISO 13485:2016 harmonized standard specifies the requirements for a quality management system where an organization must demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Based on the ISO 9001 process model, ISO 13485 includes particular elements needed for organizations involved in the lifecycle of medical devices. The Intelligent Fingerprinting business has also been recertified for the ISO 9001:2015 quality standard.

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 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 worldwide, 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 United States Food and Drug Administration), 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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