

**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 5, 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, 41<sup>st</sup> Street, 5<sup>th</sup> 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 September 5, 2024, Intelligent Bio Solutions Inc. (the “Company”) issued a press release (the “Press Release”) announcing progress toward the completion of the clinical study plan required for its FDA 510(k) submission. 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.**

<b>No.</b>	<b>Description</b>
99.1	<a href="#">Press release dated September 5, 2024</a>
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 5, 2024

**INTELLIGENT BIO SOLUTIONS INC.**

By: /s/ Spiro Sakiris

Name: Spiro Sakiris

Title: Chief Financial Officer

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**Intelligent Bio Solutions Inc. Announces Progress Toward Completion of Clinical Study Plan Required for FDA 510(k) Submission**

**NEW YORK, September 05, 2024** – Intelligent Bio Solutions Inc. (Nasdaq: INBS) (“INBS” or the “Company”), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced its progress toward completion of the clinical study plan required for its FDA 510(k) submission.

In August 2024, INBS announced its partnership with CenExel to perform the method comparison study as part of the Company’s clinical study plan. The study involves the recruitment of 135 healthy adult subjects across three sites under an IRB-approved protocol and comparing the results of fingerprint sweat opiate screening tests with those obtained using a validated, traceable liquid chromatography-mass spectrometry (LC-MS/MS) method in a laboratory.

The Company has successfully completed approximately one-third of the subject enrollment targets for its method comparison study, including screening, consenting, and fingerprint sweat specimen collection activities. Additionally, the Company recently completed the in-clinic portion of a pharmacokinetic (PK) study on opiates in human fingerprint sweat and is currently analyzing the collected specimens and data from the study.

Harry Simeonidis, President and CEO at INBS, commented, “Our team and CRO partner are working together effectively to remain on track with our plan to complete the in-clinic portion of the method comparison study by the end of September. This progress aligns with our overarching goal of preparing a 510(k) submission for the FDA in the fourth calendar quarter of 2024.”

Through these clinical studies, the Company intends to demonstrate that the Intelligent Fingerprinting Drug Screening System is easy to use and performs accurately in the hands of intended users to detect the presence of opiates.

**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 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. Additionally, the Company’s biosensor platform has the potential to test for various indications, ranging from immunological conditions to 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/>

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**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.

**Company Contact:**

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**Investor & Media Contact:**

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