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): August 1, 2024

INTELLIGENT BIO SOLUTIONS INC.

(Exact name of registrant as specified in its charter)

001-39825

Delaware

82-1512711

(Commission File Number) (IRS employer identification no.) (State of Incorporation) 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 142 West, 57th Street, 11th Floor, New York, NY 10019 (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 August 1, 2024, Intelligent Bio Solutions Inc. (the "Company") issued a press release (the "Press Release") announcing that CenExel, a nationwide clinical research site network, will perform a method comparison clinical study as part of the Company's FDA 510(k) clinical study plan. 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 August 1, 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: August 1, 2024

INTELLIGENT BIO SOLUTIONS INC.

By: /s/ Spiro Sakiris
Name: Spiro Sakiris

Title: Chief Financial Officer

Intelligent Bio Solutions Partners with CenExel to Conduct Clinical Study as Part of FDA 510(k) Pathway

NEW YORK, August 1, 2024 – <u>Intelligent Bio Solutions Inc.</u> (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced its partnership with <u>CenExel</u>, a nationwide clinical research site network, to perform a method comparison clinical study as part of the Company's FDA 510(k) clinical study plan.

The Company's method comparison study will recruit 135 healthy adult subjects across three sites under an IRB-approved protocol and compare the results of fingerprint sweat opiate screening tests to the results from a validated, traceable liquid chromatography mass spectrometry (LC-MS/MS) method, widely accepted as the gold standard for such studies.

Harry Simeonidis, President and CEO of Intelligent Bio Solutions, commented, "We are pleased to announce our partnership with CenExel and the initiation of the method comparison study, marking the final phase in our clinical study plan. Over the past two months, we have made substantial progress and are steadily getting closer to filing our 510(k) submission with the FDA. We remain on track for our planned submission to the FDA in the fourth quarter of this calendar year. I commend our dedicated team and clinical study partners for their immense effort and commitment to ensuring the smooth execution of our clinical study plan." Stuart Goldblatt, Chief Executive Officer at CenExel, stated, "CenExel is excited to commence this clinical trial to test this innovative device with the potential to provide rapid and non-invasive testing for opiates."

The Company recently completed the in-clinic portion of a pharmacokinetic (PK) study on opiates in human fingerprint sweat. Through the method comparison study, the Company intends to demonstrate that the <u>Intelligent Fingerprinting Drug Screening System</u>, which comprises the Intelligent Fingerprinting Drug Screening Cartridge and DSR-Plus fluorescence reader, performs accurately in the hands of intended users to detect the presence of opiates. The Company plans to commence the method comparison study in August 2024.

About CenExel

CenExel provides unparalleled medical and scientific support in the design and execution of clinical trials. CenExel's therapeutic area focus, attention to detail, and auxiliary services assure quality, reliable results and help it to consistently achieve and exceed patient recruitment goals. CenExel Centers of Excellence have conducted thousands of studies, the variety and complexity of which have resulted in a vast depth of experience and insight for the Principal Investigators and research staff in each facility. The CenExel Centers of Excellence deliver the engagement, expertise, and results to ensure clients achieve their clinical research goals.

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/

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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