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): **April 7, 2025**

iBio, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of incorporation)

001-35023	**26-2797813**
(Commission File Number)	*(IRS Employer Identification No.)*

11750 Sorrento Valley Road Suite 200
San Diego, California 92121
(Address of principal executive offices and zip code)

(979) 446-0027
(Registrant's telephone number including area code)

N/A
(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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(b) 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, $0.001 par value per share	IBIO	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark 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 April 7, 2025, iBio, Inc., (the "Company") issued a press release announcing data from a non-human primate study of IBIO-600, the Company's long-acting anti-myostatin antibody, and preclinical data of a first-in-class Activin E antibody. A copy of the press release is furnished herewith as Exhibit 99.1.

The non-human primate data showed extended half-life and muscle growth. The results indicate IBIO-600 promoted a dose-dependent increase in lean mass and a reduction in fat mass from baseline values. Standard PK calculations indicated the half-life of IBIO-600 in non-human primates was 40 to 52 days**.** Non-human primate pharmacokinetics data suggests IBIO-600, a potentially best-in-class long-acting anti-myostatin antibody, could have a human half-life as long as 130 days.

Preclinical data for a first-in-class Activin E antibody disclosed in January, showed that the antibody effectively blocks Activin E signaling in human adipocytes and is currently being evaluated in an exploratory study with obese mice, both as a monotherapy with bi-weekly dosing and in combination with semaglutide dosed daily. After only two weeks of dosing, monotherapy resulted in fat-selective weight loss of approximately 4%, with a significant 18% reduction in total body fat compared to placebo. Notably, when combined with semaglutide, the Activin E antibody demonstrated a strong synergistic effect, enhancing total weight loss by an additional 9% beyond GLP-1 therapy alone, leading to an overall weight reduction of 34%. This combination also resulted in a remarkable 72% reduction in body fat over the treatment period, as measured by DEXA scans.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") and shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On April 7, 2025, the Company issued a press release announcing data from a non-human primate study of IBIO-600, the Company's long-acting anti-myostatin antibody, and preclinical data of a first-in-class Activin E antibody. A copy of the press release is furnished herewith as Exhibit 99.1.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated April 7, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 7, 2025

IBIO, INC.

By: /s/ Marc A. Banjak
Name: Marc A. Banjak
Title: Chief Legal Officer

iBio Announces IBIO-600 Non-Human Primate Data Showing Extended Half-Life and Muscle Growth, and Interim In Vivo Results for First-in-Class Activin E Antibody, Advancing Cardiometabolic and Obesity Pipeline

Non-human primate pharmacokinetics data suggests IBIO-600, a potentially best-in-class long-acting anti-myostatin antibody, could have a human half-life as long as 130 days

Additional interim in vivo data for a first-in-class Activin E antibody shows muscle sparing weight loss alone and in combination with a GLP-1 receptor agonist

iBio remains on track to submit a regulatory submission for IBIO-600 in Q1 2026.

SAN DIEGO, Apr. 7, 2025 (GLOBE NEWSWIRE) -- iBio, Inc. (Nasdaq: IBIO), an AI-driven innovator of precision antibody therapies, today announced data from a non-GLP non-human primate (NHP) pharmacokinetics (PK) study suggesting IBIO-600, the company's novel lead asset and a potentially best-in-class long-acting anti-myostatin antibody designed for subcutaneous administration, could provide a significantly extended half-life in humans and a weight loss treatment option while preserving and promoting muscle growth.

The results were observed in a recently completed exploratory study in obese and elderly NHPs designed to analyze the potential of IBIO-600 in NHPs in order to closely mimic the human obese patient population by determining the antibody's half-life in serum and evaluating changes in lean and fat mass. The study consisted of two dose levels, a low dose of 5 mg/kg and a high dose of 50 mg/kg, with a single administration in each case. In addition to monitoring PK in serum, the study analyzed body composition changes over time by employing DEXA scans, measuring lean and fat mass.

Despite the study not being powered to demonstrate statistical significance, and only having a single administration of the antibody, the results indicate IBIO-600 promoted a dose-dependent increase in lean mass and a reduction in fat mass from baseline values. The effect peaked after 8 weeks, when the NHPs receiving the low-dose had a **3.1% (163g)** increase in lean mass and a **5.1% (270g)** increase in the NHPs receiving the high-dose.

Standard PK calculations indicated the half-life of IBIO-600 in NHPs was 40 to 52 days. By using multiple allometric scaling approaches[1,2], the half-life in humans of IBIO-600 has an estimated range of 57-130 days. This extended half-life could potentially enable a once every 3 to 6-month dosing schedule and positions IBIO-600 as a best-in-class therapeutic for muscle preservation and high-quality weight loss.

"The promising data suggest IBIO-600 could possibly exhibit the longest half-life among any other anti-myostatin candidates — potentially leading to best-in-class muscle preservation and growth with a significantly reduced dosing burden for patients with a few doses a year," said Martin Brenner, Ph.D., DVM, iBio's CEO and Chief Scientific Officer. "IBIO-600's extended half-life and muscle-building potential make it a transformative candidate for high-quality weight loss, further strengthening our expanding cardiometabolic and obesity pipeline. It is truly remarkable we've been able to advance this potentially best-in-class long-acting anti-myostatin antibody to clinical candidate selection in under a year and remain fully on track for a regulatory submission in Q1 2026. This incredibly rapid progress highlights our commitment to accelerating innovation and redefining obesity treatment with cutting-edge therapeutics."

iBio is also pleased to announce preclinical data for a first-in-class Activin E antibody disclosed in January, highlighting its potential as a novel treatment for obesity. The antibody effectively blocks Activin E signaling

in human adipocytes and is currently being evaluated in an exploratory study with obese mice, both as a monotherapy with bi-weekly dosing and in combination with semaglutide dosed daily. After only two weeks of dosing, monotherapy resulted in fat-selective weight loss of approximately 4%, with a significant 18% reduction in total body fat compared to placebo. Notably, when combined with semaglutide, the Activin E antibody demonstrated a strong synergistic effect, enhancing total weight loss by an additional 9% beyond GLP-1 therapy alone, leading to an overall weight reduction of 34%. This combination also resulted in a remarkable 72% reduction in body fat over the treatment period, as measured by DEXA scans. These compelling findings underscore the potential of Activin E inhibition as a transformative approach to obesity treatment, supporting further development and clinical advancement.

[1]Genki Nakamura, Kazuhisa Ozeki, Miho Nagayasu, Takeru Nambu, Takayuki Nemoto, Ken-ichi Hosoya, Predicting Method for the Human Plasma Concentration–Time Profile of a Monoclonal Antibody from the Half-life of Non-human Primates, Biological and Pharmaceutical Bulletin, 2020, Volume 43, Issue 5, Pages 823-830, Released on J-STAGE May 01, 2020, Online ISSN 1347-5215, Print ISSN 0918-6158, https://doi.org/10.1248/bpb.b19-01042, https://www.jstage.jst.go.jp/article/bpb/43/5/43_b19-01042/_article/-char/en

[2] Haraya K, Tachibana T. Translational Approach for Predicting Human Pharmacokinetics of Engineered Therapeutic Monoclonal Antibodies with Increased FcRn-Binding Mutations. BioDrugs. 2023 Jan;37(1):99-108. doi: 10.1007/s40259-022-00566-2. Epub 2022 Nov 30. PMID: 36449140; PMCID: PMC9709760.

About iBio, Inc.

iBio (Nasdaq: IBIO) is a cutting-edge biotech company leveraging AI and advanced computational biology to develop next-generation biopharmaceuticals for cardiometabolic diseases, obesity, cancer and other hard-to-treat diseases. By combining proprietary 3D modeling with innovative drug discovery platforms, iBio is creating a pipeline of breakthrough antibody treatments to address significant unmet medical needs. Our mission is to transform drug discovery, accelerate development timelines, and unlock new possibilities in precision medicine. For more information, visit www.ibioinc.com or follow us on LinkedIn.

FORWARD-LOOKING STATEMENTS

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. These forward-looking statements are based upon current estimates and assumptions and include statements regarding non-human primate pharmacokinetics data suggesting IBIO-600, a potentially best-in-class long-acting anti-myostatin antibody, could have a human half-life as long as 130 days; remaining on track to submit a regulatory submission for IBIO-600 in Q1 2026; IBIO-600 providing a significantly extended half-life in humans and a weight loss treatment option while preserving and promoting muscle growth; the extended half-life potentially enabling a once every 3 to 6-month dosing schedule and positioning IBIO-600 as a best-in-class therapeutic for muscle preservation and high-quality weight loss; IBIO-600 possibly exhibiting the longest half-life among any other anti-myostatin candidates — potentially leading to best-in-class muscle preservation and growth with a significantly reduced dosing burden for patients with a few doses a year; IBIO-600's extended half-life and muscle-building potential making it a transformative candidate for high-quality weight loss, further strengthening our expanding cardiometabolic and obesity pipeline; and the potential of Activin E inhibition as a transformative approach to obesity treatment, supporting further development and clinical advancement. While iBio believes these forward-looking statements are reasonable, undue reliance

should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are subject to various risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability of IBIO-600 to have a half-life as long as 130 days; the ability of iBio's innovative pipeline of therapeutics in cardiometabolic disease and obesity to promote healthy weight loss and muscle-building; and iBio's ability to create a pipeline of breakthrough antibody treatments to address significant unmet medical needs; iBio's ability to obtain regulatory approvals for commercialization of its product candidates, or to comply with ongoing regulatory requirements; regulatory limitations relating to iBio's ability to promote or commercialize its product candidates for specific indications; acceptance of iBio's product candidates in the marketplace and the successful development, marketing or sale of products; and whether iBio will incur unforeseen expenses or liabilities or other market factors; and the other factors discussed in iBio's filings with the SEC including its Annual Report on Form 10-K for the year ended June 30, 2024 and its subsequent filings with the SEC on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and iBio undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

Corporate Contact:

iBio, Inc.
Investor Relations
ir@ibioinc.com

Media Contacts:

Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310 or (646) 942-5604