

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): July 15, 2021

**iBio, Inc.**

(Exact name of registrant as specified in charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-35023**

(Commission File Number)

**26-2797813**

(IRS Employer Identification No.)

**8800 HSC Parkway  
Bryan, Texas 77807**

(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 July 15, 2021, iBio, Inc. (the "Company") issued a press release announcing that preclinical studies of IBIO-202, its subunit vaccine candidate that targets the nucleocapsid protein ("N protein") of SARS-CoV-2, have demonstrated robust antigen-specific, memory T-cell response.

The information in this Item 7.01 and in the press release attached 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 information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. 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.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

**Item 8.01. Other Events**

The Company today announced that preclinical studies of IBIO-202, its subunit vaccine candidate that targets the nucleocapsid protein (“N protein”) of SARS-CoV-2, have demonstrated robust antigen-specific, memory T-cell response. A strong, cytotoxic, memory T-cell response was seen in the IBIO-202 immunization data. In addition, T-cell priming was achieved via both intramuscular and intranasal administration, allowing for the further exploration of multiple routes of administration and their respective benefits. Data from the preclinical studies are attached as Exhibit 99.2.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K.

Exhibit Number	Exhibit Description
<a href="#">99.1</a>	<a href="#">Press Release dated July 15, 2021</a>
<a href="#">99.2</a>	<a href="#">Preclinical Data</a>

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**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.

**IBIO INC.**

Date: July 16, 2021

By: /s/ Thomas F. Isett  
Name: Thomas F. Isett  
Title: Chairman and Chief Executive Officer

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**iBio Reports Successful Preclinical Immunization Studies with Next-Gen Nucleocapsid COVID-19 Vaccine Candidate**

Bryan, TX / July 15, 2021 / (GLOBE NEWSWIRE) / iBio, Inc. (NYSE:IBIO) (“iBio” or the “Company”), a biotech innovator and biologics contract manufacturing organization, today announced that preclinical studies of IBIO-202, its subunit vaccine candidate that targets the nucleocapsid protein (“N protein”) of SARS-CoV-2, demonstrated a robust, antigen-specific, memory T-cell response.

Data on commercially available COVID-19 vaccines - all of which target the spike protein (“S protein”) - suggests that neutralizing titers are effective, but likely to wane over time. In addition, the robustness of T-cell priming and cellular immunity achieved by S protein-directed vaccines may not be sufficient to create a durable immune response, especially in the context of emerging variant strains of the virus. In contrast, the N protein gene is more conserved and stable than the spike, with 90% amino acid homology and fewer mutations over time. Notably, the SARS-CoV-2 N protein shares substantial sequence conservation with the nucleocapsid of other coronaviruses.

It has been observed that the N protein can induce SARS-specific T-cell proliferation. The IBIO-202 immunization data are consistent with that, as a strong, cytotoxic, memory T-cell response was seen, rather than an inflammatory response. In addition, T-cell priming was achieved via both intramuscular and intranasal administration, allowing for the further exploration of multiple routes of administration and their respective benefits.

“Studies of convalescent sera from patients that have recovered from SARS-CoV-2 infection have shown that the combination of N-directed and S-directed immunity is important,” said Martin Brenner, DVM. Ph.D., iBio’s CSO. “Accordingly, we believe the N protein strategy of IBIO-202 may be complementary with existing S-directed vaccines, conferring additional protective effects that more closely mimic the natural immune responses of patients that have cleared the virus.”

Additional characterization studies of IBIO-202 are ongoing.

**About iBio, Inc.**

iBio is a global leader in plant-based biologics manufacturing. Its **FastPharming** System<sup>®</sup> combines vertical farming, automated hydroponics, and novel glycosylation technologies to rapidly deliver high-quality monoclonal antibodies, vaccines, bioinks and other proteins. iBio is developing proprietary products which include biopharmaceuticals for the treatment of cancers, as well as fibrotic and infectious diseases. The Company’s subsidiary, iBio CDMO LLC, provides **FastPharming** Contract Development and Manufacturing Services along with **Glycanearing** Development Services<sup>™</sup> for advanced recombinant protein design. For more information, visit [www.ibioinc.com](http://www.ibioinc.com).

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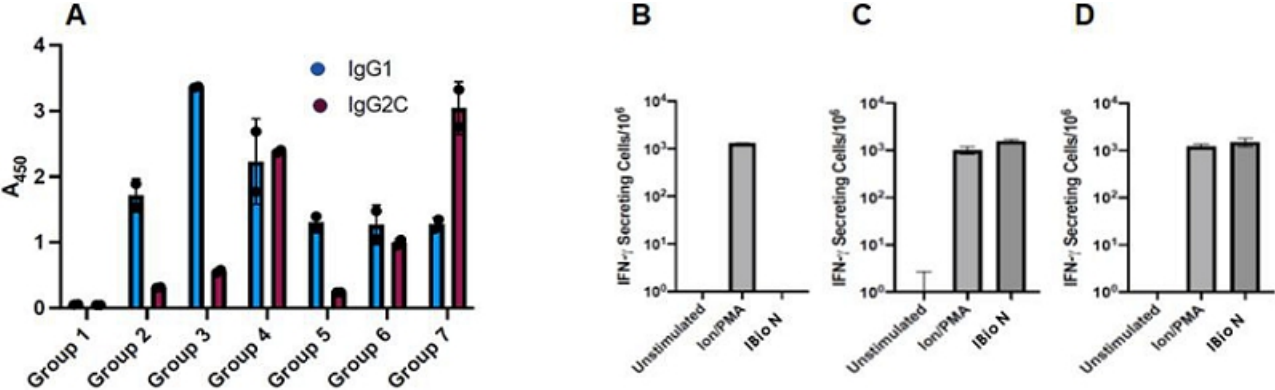
**FORWARD-LOOKING STATEMENTS**

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 the potential of IBIO-202, the N protein strategy of IBIO-202 being complementary with existing S protein directed vaccines, conferring additional protective effects that more closely mimic the natural immune responses of patients that have cleared the virus and plans to complete additional characterization studies of IBIO-202. While the Company 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 Company’s ability to successfully complete additional testing planned for IBIO-202, the N protein strategy of IBIO-202 being complementary with existing S protein directed vaccines, the Company’s ability to obtain regulatory approvals for commercialization of its product candidates, including its COVID-19 vaccines, or to comply with ongoing regulatory requirements, regulatory limitations relating to its ability to promote or commercialize the Company’s product candidates for specific indications, acceptance of the Company’s product candidates in the marketplace and the successful development, marketing or sale of the Company’s products, the Company’s ability to maintain its license agreements, the continued maintenance and growth of its intellectual property portfolio, the Company’s ability to establish and maintain collaborations, the Company’s ability to obtain or maintain the capital or grants necessary to fund its research and development activities, competition, the Company’s ability to retain its key employees or maintain its NYSE American listing, and the other risk factors discussed in the Company’s most recent Annual Report on Form 10-K and the Company’s subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and we undertake 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.

**Contact:**

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Mice were immunized with iBio's SARS-CoV-2 nucleocapsid (N) vaccine candidate in combination with several adjuvants, leading to robust and differentiated immune responses. Th-1 skewed N-specific antibody titers were observed in antigen/adjuvant combinations following intramuscular injection, notably Groups 4 and 7 (panel A). Robust T cell priming was measured by ELISpot for multiple antigen/adjuvant combinations (C and D, as examples), while immune cells from a naïve mouse showed no response to exposure to the N antigen (B).