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 16, 2022**

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.)*

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 August 16, 2022, iBio, Inc. (the "Company") issued a press release announcing it recently completed its first manufacturing run of its proprietary nucleocapsid antigen under cGMP conditions using its ***FastPharming***® Manufacturing System. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 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 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	iBio, Inc. Press Release dated August 16, 2022
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.

IBIO INC.

Date: August 16, 2022

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

Exhibit 99.1

iBio Provides Update on Development of Next-Gen COVID-19 Vaccine Candidate

- Manufactured first batch of drug substance under cGMP conditions -

- Analysis of challenge study data underway -

Bryan, Texas / August 16, 2022 / (GLOBE NEWSWIRE) / iBio, Inc. (NYSEA:IBIO) ("iBio" or the "Company"), a developer of next-generation biopharmaceuticals and pioneer of the sustainable ***FastPharming***® Manufacturing System, today provided an update on IBIO-202, its next-generation vaccine candidate under development for multi-variant COVID-19 disease.

The Company recently completed its first manufacturing run of its proprietary nucleocapsid antigen under cGMP conditions using its ***FastPharming*** System. Unlike commercially available first-generation COVID vaccines that seek to provide immunity by presenting an antigen based on the frequently mutating spike ("S") protein - which results in waning periods of immunity and the spread of new variants[1] - IBIO-202 uses a portion of the nucleocapsid ("N") protein, which is more highly conserved.[2] The recently produced N antigen is currently undergoing release testing and, if it clears, is intended for use in IBIO-202 clinical studies.

"This is another important step in our mission to develop a 'last dose', not a 'next dose' of a COVID-19 vaccine," said Tom Isett, Chairman & CEO of iBio. "We believe there is a substantial unmet need for a vaccine that protects against existing - and potentially new - variants and for longer periods of time. While currently available spike protein-based COVID-19 vaccines have undoubtedly prevented severe disease and deaths for millions of people, hospitalizations and deaths have nevertheless again been on the rise recently in the U.S.[3] This is primarily attributable to mutations specific to the virus' spike protein, like those associated with the BA.5 variant, that result in existing vaccines providing less protection or shorter periods of immunity."

During the July 26 *Summit on the Future of COVID Vaccines*, these recent developments prompted Raj Panjabi, MD, MPH, Director of the White House Pandemic Preparedness Office, to state that, "Predicting where the virus is going to go is hard, but so is asking people to get vaccinated two or three times a year. That is a huge challenge. So, we need vaccines that are durable. We need vaccines that offer broader and longer lasting protection. We need vaccines that offer protection against multiple variants. Ultimately, we need vaccines that can protect us no matter what mother nature throws at us."[3]

Last month, Chair of the Senate Appropriations Committee, Patrick Leahy (D-VT), in partnership with the Subcommittee Chairs responsible for domestic health care and global health, Patty Murray (D-WA) and Chris Coons (D-DE), introduced a $21 billion supplemental funding bill to provide necessary resources to prepare for the next phase of the COVID-19 pandemic and address other emerging infectious diseases. This important legislation incudes $750 million for next-generation COVID-19 vaccines to protect against variants of concern for today and tomorrow and emphasizes the need to support, and increase, domestic manufacturing capacity.

"We continue to engage directly with these and other Members of Congress on funding opportunities for next-generation COVID-19 vaccines," added Mr. Isett. "In addition, we regularly maintain direct dialogue with Administration officials on the need for, and value of, funding iBio's work in this field."

Additionally, iBio confirmed it is currently compiling and analyzing initial data from investigational new drug ("IND")-Enabling challenge studies of IBIO-202.

About iBio's COVID-19 Vaccine Development Program

In November 2020, iBio began exploring a second-generation COVID-19 vaccine program based on the N protein. In July 2021, iBio announced positive results from dose ranging, preclinical studies that demonstrated IBIO-202 could generate a robust, antigen-specific, memory T-cell response. In addition, T-cell priming was achieved via both intramuscular and intranasal administration, allowing further exploration of multiple routes of administration and their respective benefits. In September 2021, iBio submitted a pre-IND package for IBIO-202 to the FDA. In November 2021, the Company announced it entered into a collaboration agreement with a leading innovator of microarray patch systems in order to evaluate feasibility of intradermal delivery of a COVID-19 vaccine antigen. Based on feedback it received from the FDA, in January 2022, iBio announced it was pursuing IND-Enabling studies for IBIO-202, delivered intramuscularly. Today, the Company announced it completed its first manufacturing run of its proprietary nucleocapsid antigen under cGMP conditions in support of IBIO-202 drug substance production. More information on the COVID-19 vaccine program can be found on the Company's website.

The Scientific Rationale Behind Targeting the N Protein of SARS-CoV-2

iBio believes the N protein represents an important target for next-generation COVID-19 vaccines for several reasons. First, the N protein is abundantly expressed during infection and contains multiple immunogenic epitopes. Second, the N protein is more highly conserved than the S protein, and therefore, new variants may be less likely to escape vaccine protection. Third, research has shown

the N protein appears to be significantly more effective than the S protein in stimulating antibody-dependent natural killer cell activation, a critical element of the adaptive immune response that the SARS-CoV-2 virus attempts to evade.[2,4,5,6,7]

References

[1] Goldberg, et al. Protection and waning of natural and hybrid COVID-19 immunity.https://www.medrxiv.org/content/10.1101/2021.12.04.21267114v1

[2] Dutta, N. K., Mazumdar, K. & Gordy, J. T. The Nucleocapsid Protein of SARS–CoV-2: A Target for Vaccine Development. Journal of Virology 94, (2020).

[3] https://bestlifeonline.com/fauci-covid-vaccines-next-generation-news/

[4] Zhao, P. et al. Immune responses against SARS-coronavirus nucleocapsid protein induced by DNA vaccine. Virology 331, 128–135 (2005).

[5] Oliveira, S. C., de Magalhães, M. T. Q. & Homan, E. J. Immunoinformatic Analysis of SARS-CoV-2 Nucleocapsid Protein and Identification of COVID-19 Vaccine Targets. Front. Immunol. 11, (2020).

[6] Dai, L. & Gao, G. F. Viral targets for vaccines against COVID-19. Nature Reviews Immunology 21, 73–82 (2021).

[7] Fielding CA, Sabberwal P, Williamson JC, Greenwood EJD, Crozier TWM, Zelek W, Seow J, Graham C, Huettner I, Edgeworth JD, Morgan BP, Ladell K, Eberl M, Humphreys IR, Merrick B, Doores K, Wilson SJ Lehner PJ, Wang ECY, Stanton RJ. ADNKA overcomes SARS-CoV2-mediated NK cell inhibition through non-spike antibodies. bioRxiv, (April 2021).

About iBio, Inc.

iBio is a developer of next-generation biopharmaceuticals and a pioneer in sustainable, plant-based biologics manufacturing. Its ***FastPharming***® System 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 biopharmaceuticals for the treatment of cancers, as well as fibrotic and infectious diseases. The Company's wholly-owned subsidiary, iBio CDMO LLC, provides ***FastPharming*** Contract Development and Manufacturing Services along with ***Glycaneering***SM Development Services for advanced recombinant protein design. For more information, visitwww.ibioinc.com.

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 a next-generation vaccine development strategy such as the Company's mission to develop a 'last dose', not a 'next dose' of a COVID-19 vaccine; N-, not S-, reactive T cells playing a protective role for SARS-CoV-2 and potentially other betacoronaviruses as well; there being a substantial unmet need for a vaccine that protects against existing - and potentially new - variants and for longer periods of time; continuing to engage directly with these and other Members of Congress on funding opportunities for next-generation COVID-19 vaccines; and the N protein representing an important target for next-generation COVID-19 vaccines for several reasons. 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 the Company 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 develop IBIO-202 as a vaccine that can provide better protection against future variants; iBio's prospect to secure funding opportunities for next-generation COVID-19 vaccines from Congress; iBio's ability to obtain regulatory approvals for commercialization of IBIO-202 and its other product candidates, or to comply with ongoing regulatory requirements; regulatory limitations relating to its ability to promote or commercialize its product candidates for specific indications; acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products; and the other factors discussed in the Company's filings with the SEC including the Company's Annual Report on Form 10-K for the year ended June 30, 2021 and the Company's 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 the Company 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.

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