

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 27, 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 2.02. Results of Operations and Financial Condition.

On September 27, 2021, iBio, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter and year ended June 30, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 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 in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit Number	Exhibit Description
99.1	<u>Press Release, issued by iBio, Inc. dated September 27, 2021</u>

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: September 27, 2021

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

iBio Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Corporate Update

Expanded Immuno-Oncology Pipeline with License of Next-Gen anti-CD25 Antibody for Solid Tumors

*Paired Access to RubrYc's Antibody Discovery Platform with **FastPharming**[®] and **Glycaneering**[™] Platforms to Accelerate Drug Development*

Advanced COVID-19 Nucleocapsid-based Vaccine Candidate with pre-IND Submission

Bryan, Texas / September 27, 2021 / (GLOBE NEWSWIRE) / iBio, Inc. (NYSEA:IBIO) ("iBio" or the "Company"), a developer of next-generation biopharmaceuticals and pioneer of the sustainable, plant-based **FastPharming** Manufacturing System[®], today announced its financial results for the fiscal fourth quarter and year ended June 30, 2021.

"Fiscal 2021 was a transformative period for iBio, highlighted by our entry into oncology and continued progress as a next-gen COVID-19 vaccine developer," said Tom Isett, Chairman & CEO of iBio. "In the fiscal fourth quarter, we established our new oncology drug discovery team in San Diego. Subsequently, we entered into a partnership with FairJourney Biologics that provides us access to proprietary antibodies and announced the addition of three new anti-cancer targets to our pipeline. Then in August, we announced an exclusive license agreement with RubrYc Therapeutics for a second generation anti-CD25 antibody for the treatment of solid tumors. This collaboration also provides us access to RubrYc's AI-driven antibody discovery platform, which should enable iBio to develop multiple novel immuno-oncology targets. Coupled with our **FastPharming** and **Glycaneering** Technologies, we believe iBio is now well positioned to capture discovery and development synergies across these proprietary platforms, enabling us to further build our pipeline of differentiated, next-gen oncology therapeutics."

"Although we are pleased to have executed on our November promise to build a high-value oncology portfolio, we are even more pleased to deliver results in other areas of our Biopharmaceutical segment, especially our next-generation COVID-19 vaccine, IBIO-202. We believe that there is a critical need to design new vaccines that can target regions of the virus aside from the frequently mutating spike protein, in order to address the looming risk of an escape variant. IBIO-202 could potentially represent one such option, given that it targets the more highly conserved nucleocapsid protein of SARS-CoV-2, and in preclinical models of disease, drove robust memory T cell responses. We look forward to updating investors on IBIO-202 after we receive feedback on our pre-IND package, which was submitted earlier this month."

"While we were aggressively building our Biopharmaceutical segment and recruiting our new Management Team in FY21, we also grew our Bioprocess segment. Revenues in the Services business were up 50% over prior year. We also established a new 'Products' business unit to further exploit our **FastPharming** System and capabilities to deliver greener products to researchers and biomanufacturers. All things considered, this past year was one of exceptional achievement towards creating a multifaceted business that fully leverages our technologies and capabilities to help iBio and our customers address unmet medical needs in the fields of oncology, fibrosis, and infectious diseases."

Fiscal Fourth Quarter and Recent Business Developments:BIOPHARMACEUTICAL SEGMENT

Therapeutics

- In June 2021, iBio established a new drug discovery team based in San Diego.
- In July 2021, iBio added three new antibody programs to its oncology drug discovery pipeline.
- In August 2021, the Company signed a definitive worldwide exclusive license agreement with RubrYc Therapeutics, Inc., for a monoclonal antibody candidate designed to deplete immunosuppressive regulatory T cells from the tumor microenvironment. Additionally, iBio acquired an equity stake in RubrYc along with an option to license antibodies developed with RubrYc's artificial intelligence ("AI")-based antibody discovery platform.
- iBio continues pre-clinical development of IBIO-100. The Company expects to initiate IND-enabling studies during FY 2022.
- For regulatory and business reasons, the Company discontinued development of its discovery-stage ACE2-Fc project.

Vaccines

- In July 2021, the Company reported robust, antigen-specific, memory T-cell responses from preclinical studies of IBIO-202.
- In September 2021, iBio submitted a pre-IND package for IBIO-202 with the expectation that a nucleocapsid-based protein subunit vaccine could address several unmet needs that remain with first-generation vaccines targeting the spike protein.
- The Company is continuing to develop its Classical Swine Fever Vaccine, IBIO-400, while concurrently seeking regulatory clearances for the animal health markets.

BIOPROCESS SEGMENT

Services

- In May 2021, iBio announced that it concluded its lawsuit with Fraunhofer USA, Inc. One outcome of the settlement was that iBio received a \$1.8 million fee in exchange for a license to Fraunhofer for use of certain iBio trade secrets relating to the **FastPharming** System. The Company expects to recognize the license fee as Services revenues in the future. Another outcome of the case was that iBio realized, net of legal fees and other expenses, Settlement Income of \$10.2 million.
- The Company also announced in May an expanded menu of Bioanalytical Services, including intact protein analysis, new proteomic assays, and middle-down characterization for monoclonal antibodies.

Products

- In June 2021, iBio launched a new line of growth factors, cytokines and lectins via its new e-shop. The Company plans to add more **FastPharming**-produced recombinant proteins to the catalog over time, including monoclonal antibodies for research that are scalable for cGMP bioprocessing uses.

Fiscal Fourth Quarter and Recent Corporate Developments:

- Throughout fiscal 2021 and FY22 year-to-date, iBio increased its bench strength and enhanced its leadership team to support its growth strategy. Overall staffing grew by approximately 60% to 87 employees, with new hiring focused in the areas of drug discovery, process development, and finance. Between December and March, the Executive Team was increased from one member to five.
- In June 2021, the Company further strengthened its Board of Directors with the appointment of Evert (Eef) Schimmelpennink, who has a strong history of success leading companies with novel protein expression platforms to develop and commercialize biopharmaceutical products.
- In August 2021, iBio appointed William D. (Chip) Clark to its Board, adding deep expertise in business management and immuno-oncology. Also in August, Seymour Flug resigned from the Board.
- iBio recently presented at the UBS Global Healthcare Virtual Conference and the H.C. Wainwright 23^d Annual Global Investment Conference. Today, the Company is scheduled to participate in a fireside chat at the Cantor Virtual Global Healthcare Conference.

Financial Results:

Revenues for the fiscal year ended June 30, 2021, were \$2.4 million, an increase of 50% over fiscal 2020. In the fourth quarter ended June 30, 2021, revenue was \$0.5 million, a decrease of \$0.6 million from Q4 FY2020, and a decrease of \$0.3 million from Q3 FY2021. Significant quarter-to-quarter revenue variability is commonplace for early-stage pharma services companies, given the relatively small number of contracts and timing of revenue recognition. Based upon the current outlook, iBio expects a sequential decline in revenue during the first half of fiscal 2022 compared to the second half of fiscal 2021, followed by higher growth in the second half of fiscal 2022. Irrespective of quarterly fluctuations, continued year-on-year revenue growth is anticipated as the Bioprocess businesses continue to attract interest from organizations wishing to rapidly develop biologics using more sustainable manufacturing methods.

R&D and G&A expenses for the fourth quarter and full fiscal year 2021 increased significantly over the comparable periods in fiscal year 2020. R&D expense was up \$6.4 million to \$10.0 million in fiscal 2021, with an increase of \$2.5 million to \$3.1 million in the fourth quarter. G&A expense was up \$10.6 million to \$22.0 million in fiscal 2021, rising \$3.5 million to \$6.6 million in the fourth quarter. The growth in R&D and G&A reflects the strategy to invest in iBio's proprietary biopharmaceutical pipeline and platform technology. Across R&D and G&A, the company invested in additional staff and made external investments to implement its strategy. While iBio expects R&D and G&A will continue to grow in fiscal 2022, it anticipates a slower growth rate compared to fiscal 2021.

In the fourth quarter of fiscal 2021, iBio recorded \$10.2 million in Settlement Income, reflecting the value of settlement of litigation with Fraunhofer. While iBio recognized this income in fiscal 2021, actual payment by Fraunhofer will be made in two separate payments of \$5.1 million each in March 2022 and March 2023. Fraunhofer also agreed to pay iBio \$1.8 million for a license to iBio's intellectual property. Revenue for that license will be recognized when Fraunhofer pays for the license in two installments of \$0.9 million each, expected in March 2022 and March 2023.

iBio's consolidated net loss for fiscal 2021 ending June 30, 2021, was \$23.2 million, an increase of \$6.8 million compared to 2020. The increase in consolidated net loss would have been greater except for the Settlement Income of \$10.2 million recognized in the fourth quarter of 2021. iBio had a consolidated net gain of \$0.1 million in the fourth quarter because of the Settlement Income versus a consolidated net loss in Q4 FY2020 of \$3.5 million.

iBio had \$97.0 million in cash, marketable securities, and investments in debt securities as of June 30, 2021. iBio used \$30.1 million in net cash for operating activities in fiscal 2021 versus net cash used in operating activities of \$13.3 million in 2020. Based on current plans, iBio believes the current cash position is sufficient to fund operations through the first calendar quarter of 2023.

Webcast and Conference Call

iBio management will host a webcast and conference call at 8:30 a.m. Eastern Time today, September 27, 2021, to discuss these results and provide a corporate update.

The live and archived webcast may be accessed on the Company's website at www.ibioinc.com under "News and Events" in the Investors section. The live call can be accessed by dialing (833) 672-0651 (domestic) or (929) 517-0227 (international) and referencing conference code: 7159935.

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, antigens, and other proteins. iBio is developing proprietary 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 **Glycaneering** Development Services[™] for advanced recombinant protein design. For more information, visit www.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 access to RubrYc's AI-driven anti-body discovery platform enabling the Company to develop multiple novel immune-oncology targets, the Company being positioned to capture discovery and development synergies across its **FastPharming**[®] and **Glycaneering**[™] proprietary platforms, enabling it to further build its pipeline of differentiated, next-gen oncology therapeutics, the critical need to design new vaccines that target regions of SARS-CoV-2 aside from the frequently mutating spike proteins and the potential of IBIO-202 with respect thereto, initiating IND-enabling studies of IBIO-100 for systemic scleroderma during FY2022, the expectation that a nucleocapsid-based protein subunit vaccine could address several unmet needs that remain with first-generation vaccines targeting the spike protein, plans to add more **FastPharming**-produced recombinant proteins to the Company's catalog over time, including monoclonal antibodies for research that are scalable for cGMP bioprocessing uses, the expectation of a sequential decline in revenue during the first half of fiscal 2022 compared to the second half of fiscal 2021, followed by higher growth in the second half of fiscal 2022 and continued year-on-year revenue growth, expectation of continued growth of R&D and G&A in fiscal 2022 at a slower growth rate compared to fiscal 2021, current cash position being sufficient to fund operations through the first calendar quarter of 2023. 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 implement its development plans including development of multiple novel immune-oncology targets, development of IBIO-202 to successfully target regions of the SARS-Co-V-2 aside from the frequently mutating spike proteins, initiation of IND-enabling studies of IBIO-100 for systemic scleroderma during FY2022 and the addition of **FastPharming**-produced recombinant proteins to its catalog, its 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 its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products; its ability to maintain its license agreements; the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities and whether the Company will incur unforeseen expenses or liabilities or other market factors, successful compliance with governmental regulations applicable to its manufacturing facilities, competition, its ability to retain its key employees or maintain its NYSE American listing, its ability to increase its authorized shares, and the other factors discussed in the Company's filings with the SEC including the Company's most recent Annual Report on Form 10-K and the Company's subsequent filings with the SEC on Forms 10-Q and 8-K. Additional information will be set forth in the Company's Annual Report on Form 10-K for the year ended June 30, 2021. 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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iBio, Inc. and Subsidiaries
Consolidated Balance Sheets
(In Thousands, except share and per share amounts)

	<u>June 30, 2021</u>	<u>June 30, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 77,404	\$ 55,112
Accounts receivable - trade	426	75
Settlement receivable - current portion	5,100	—
Subscription receivable	—	5,549
Investments in debt securities	19,570	—
Work in progress	27	798
Prepaid expenses and other current assets	2,070	214
Total Current Assets	<u>104,597</u>	<u>61,748</u>
Note receivable and accrued interest	1,556	—
Settlement receivable - noncurrent portion	5,100	—
Finance lease right-of-use assets, net of accumulated amortization	26,111	27,616
Fixed assets, net of accumulated depreciation	8,628	3,657
Intangible assets, net of accumulated amortization	952	1,144
Security deposits	24	24
Total Assets	<u>\$ 146,968</u>	<u>\$ 94,189</u>
Liabilities and Equity		
Current liabilities:		
Accounts payable (related parties of \$0 and \$6 as of June 30, 2021 and 2020, respectively)	\$ 2,254	\$ 1,759
Accrued expenses (related party of \$701 and \$705 as of June 30, 2021 and 2020, respectively)	3,001	1,105
Finance lease obligations - current portion	367	301
Note payable - PPP loan - current portion	600	261
Deferred revenue / Contract liabilities	423	1,810
Total Current Liabilities	<u>6,645</u>	<u>5,236</u>
Note payable - PPP loan - net of current portion	—	339
Finance lease obligations - net of current portion	31,755	32,007
Total Liabilities	<u>38,400</u>	<u>37,582</u>
Commitments and Contingencies		
Equity		
iBio, Inc. Stockholders' Equity:		
Common stock - \$0.001 par value; 275,000,000 shares authorized at June 30, 2021 and 2020; 217,873,094 and 140,071,110 shares issued and outstanding as of June 30, 2021 and 2020, respectively	217	140
Additional paid-in capital	282,058	206,931
Accumulated other comprehensive loss	(63)	(33)
Accumulated deficit	(173,627)	(150,420)
Total iBio, Inc. Stockholders' Equity	<u>108,585</u>	<u>56,618</u>
Noncontrolling interest	(17)	(11)
Total Equity	<u>108,568</u>	<u>56,607</u>
Total Liabilities and Equity	<u>\$ 146,968</u>	<u>\$ 94,189</u>

iBio, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(In Thousands, except per share amounts)

	Years Ended June 30,	
	2021	2020
Revenues	\$ 2,371	\$ 1,638
Cost of goods sold	1,462	703
Gross profit	909	935
Operating expenses:		
Research and development (related party of \$0 and \$97)	9,989	3,573
General and administrative (related party of \$1,587 and \$1,143)	22,031	11,365
Total operating expenses	32,020	14,938
Operating loss	(31,111)	(14,003)
Other income (expense):		
Interest income	140	15
Interest expense (related party of \$2,446 and \$2,466)	(2,454)	(2,466)
Royalty income	12	10
Settlement income	10,200	—
Total other income (expense)	7,898	(2,441)
Consolidated net loss	(23,213)	(16,444)
Net loss attributable to noncontrolling interest	6	5
Net loss attributable to iBio, Inc.	(23,207)	(16,439)
Deemed dividends – down round of Series A Preferred and Series B Preferred	—	(21,560)
Preferred stock dividends – iBio CMO Tracking Stock	(260)	(261)
Net loss attributable to iBio, Inc. stockholders	\$ (23,467)	\$ (38,260)
Comprehensive loss:		
Consolidated net loss	\$ (23,213)	\$ (16,444)
Other comprehensive loss - unrealized loss on debt securities	(29)	—
Other comprehensive loss - foreign currency translation adjustments	(1)	(2)
Comprehensive loss	\$ (23,243)	\$ (16,446)
Loss per common share attributable to iBio, Inc. stockholders - basic and diluted	\$ (0.12)	\$ (0.61)
Weighted-average common shares outstanding - basic and diluted	195,620	62,795