UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ___ to ___

Commission file number 001-35023

iBio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2797813**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8800 HSC Parkway, Bryan, TX	**77807-1107**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(302) 355-0650**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Ticker symbol(s)**	**Name of each exchange on which registered**
Common Stock	IBIO	NYSE American

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $13,641,864 as of December 31, 2019, based upon the closing sale price on the NYSE American of $0.25 per share reported for such date.

There were 180,287,751 shares of the registrant's common stock issued and outstanding as of October 8, 2020.

DOCUMENTS INCOROPORATED BY REFERENCE:

Certain portions of the Definitive Proxy Statement to be used in connection with the Registrant's 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K

IBIO, INC.
ANNUAL REPORT ON FORM 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, references in this Annual Report on Form 10-K (this "Annual Report") to "iBio," the "Company," "we," "us," "our" and similar terms mean iBio, Inc.

Certain statements in this Annual Report, including, without limitation, statements under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements as defined in Section 27A of the Securities Act of 1933 (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), the Private Securities Litigation Reform Act of 1995 (the "PSLRA") or in releases made by the Securities and Exchange Commission (the "SEC"), all as may be amended from time to time. These cautionary statements are being made pursuant to the Securities Act, the Exchange Act and the PSLRA with the intention of obtaining the benefits of the "safe harbor" provisions of such laws. All statements contained in this Annual Report, other than statements that are purely historical, are forward-looking statements. Forward looking-statements can be identified by, among other things, the use of forward-looking language, such as the words "plans," "intends," "believes," "expects," "anticipates," "estimates," "projects," "potential," "may," "will," "would," "could," "should," "seeks," or "scheduled to," or other similar words, the negative of these terms, other variations of these terms or comparable language, or by discussion of strategy or intentions. Forward-looking statements are based upon management's present expectations, objectives, anticipations, plans, hopes, beliefs, intentions or strategies regarding the future and are subject to known and unknown risks and uncertainties that could cause actual results, events or developments to be materially different from those indicated in such forward-looking statements, including the risks and uncertainties set forth in Item 1A of this Annual Report on Form 10-K and in other securities filings by the Company. These risks and uncertainties should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements. As such, no assurance can be given that the future results covered by the forward-looking statements will be achieved. All information in this Annual Report on Form 10-K is as of June 30, 2020, unless otherwise indicated. The Company does not intend to update this information to reflect events after the date of this Annual Report.

Copies of this Annual Report, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and our other reports filed with the SEC can be obtained free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC on our website at http://www.ibioinc.com/ or directly from the SEC's website at http://www.sec.gov/. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report.

PART I

Item 1. Business.

Overview

We are a biotechnology company and biologics contract development and manufacturing organization ("CDMO"). We apply our licensed and owned technologies to develop novel products to fight fibrotic diseases, cancers, and infectious diseases. We use our *FastPharming*® Development and Manufacturing System to increase "speed-to-clinic" for new candidates. We are also using the *FastPharming* System to create proteins and bioinks for research and further manufacturing uses in a variety of research and development ("R&D") applications, including 3D-bioprinting. In addition, we make the *FastPharming* System available to clients on a fee-for-service basis for the production of proteins.

During the year ended June 30, 2020, we operated in two segments: (i) our CDMO segment, operated via our subsidiary iBio CDMO LLC ("iBio CDMO"), and (ii) our proprietary biologics development and licensing activities, conducted within iBio, Inc. In the past, our primary focus was the CDMO business, pursuant to which iBio CDMO provided manufacturing services to collaborators and third-party customers as well as to us, for our own product development purposes. However, during the second half of 2020 and subsequent to our fiscal year end, we shifted our primary focus to our proprietary biologics development programs, including novel vaccines and therapeutics.

Our current platforms and programs include: (i) CDMO services using our licensed and owned *FastPharming* Technologies and *Glycaneering*™ Services; (ii) the development of therapeutics, for which we intend to conduct preclinical and clinical trials; (iii) the development of vaccines, for which we intend to conduct preclinical and clinical trials, and (iv) the production of proteins for research and further manufacturing use in 3D-bioprinting and other applications. We are developing a portfolio of technologies, products, and services driven by the following platforms and programs, which we intend to use individually, and in combination:

- **CDMO Services**
  - Process development and manufacturing of protein products in hydroponically-grown, transiently-transfected plants, (typically *Nicotiana benthamiana,* a relative of the tobacco plant) using our proprietary expression technologies, *Glycaneering* Services, and production know-how (the *FastPharming* System), deployed in our 130,000 square-foot manufacturing facility in Bryan, Texas.
  - "Factory Solutions" for the clients who seek to insource biologics manufacturing using the *FastPharming* System instead of outsourcing production to iBio CDMO.
- **Therapeutics**
  - Treatments for fibrotic diseases, including a fusion of the endostatin-derived E4 antifibrotic peptide to the hinge and heavy chain of human IgG1 ("IBIO-100", formerly described as "CFB-03") for systemic scleroderma (for which we have received orphan drug designation), idiopathic pulmonary fibrosis, and related conditions.
  - An ACE2-Fc fusion protein to be developed as a treatment for Coronavirus disease 2019 ("COVID-19") and, prospectively, other diseases emanating from the *Coronaviridae* family, in-licensed from Planet Biotechnology, Inc.
- **Vaccines**
  - A novel virus-like particle antigen being designed for use in a vaccine candidate targeting the SARS-CoV-2 virus ("IBIO-200").
  - The lichenase ("*LicKM*™")-subunit vaccine for COVID-19 ("IBIO-201").
  - An E2 antigen, in combination with a selected adjuvant, for vaccination of pigs against classical swine fever ("IBIO-400").
- **Research & Bioprocess Products**
  - Protein scaffolds for use as bioinks in the development of 3D-bioprinted tissues and organs.
  - Cytokines and growth factors for cell culture applications.
  - Biomaterials for a range of life science research, development, and bioprocessing applications.

Our Platforms and Programs

CDMO Services

Our contract development and manufacturing services include:

Process Development	Feasibility assessment and development of manufacturing processes using the *FastPharming* Technology for optimized gene expression and purification parameters to meet client specifications for their active pharmaceutical ingredients ("APIs"). Product optimization via our *Glycaneering* Services that may be used to enhance the quality and performance of therapeutic proteins via plant-based glycosylation controls.

Manufacturing	Biologics production using the *FastPharming* System to deliver custom biologics for clinical trials.
Fill / Finish	Aseptic vial and bottle filling and finishing services with in-line labelling that provides serialization capability for greater quality assurance.
BioAnalytics	Method development and validation with expertise in protein characterization using mass spectrometry.

FastPharming® System

The *FastPharming* System is iBio's proprietary approach to plant-made pharmaceutical production. It uses iBio's *Nicotiana benthamiana* plants, novel expression vectors, a large-scale transient transfection method, and other technologies that can be used to produce complex therapeutic proteins emerging from our own, our clients' and our potential clients' pipelines. The *FastPharming* System offers several advantages versus traditional mammalian cell expression systems, including:

- **Speed:** Shorter time-to-clinic with research and clinical-scale quantities of product in weeks versus months
- **Cost-Effectiveness:** No expensive, labor-intensive or costly mammalian cell line development
- **Quality:** Consistently high-quality recombinant protein production with the ability to enhance potency for some products with powerful glycosylation controls
- **Scalability:** Each *N. benthamiana* plant is its own bioreactor, so scale-up issues are avoided by simply growing more plants
- **Safety:** Since mammalian viruses cannot replicate in plants, *FastPharming*-produced products avoid many of the risks associated with viral contamination events
- **Eco-Friendliness**: Use of plants for the protein expression process avoids the single-use plastic disposables frequently used in large volumes with mammalian expression systems

The *FastPharming* Process Technologies have been established in iBio CDMO's operations in Bryan, Texas. The process begins with robotic seeding of iBio's plants into an inert matrix for hydroponic cultivation under optimized LED lighting conditions. While the plants grow, *FastPharming* Vectors carrying the genes encoding the desired protein product are developed and then loaded into a bacterial host (*Agrobacterium tumefaciens*). Then, the bacteria carrying the vectors and DNA for producing the desired protein are introduced into the leaves of the plants via an automated vacuum infiltration process. The vectors introduce the DNA into the plant nucleus, where it is coded into instructions that direct the plant's own cellular machinery to make the desired protein. A specific arrangement of genes for plant viral enzymes causes these protein production instructions to be copied hundreds of thousands of times in each plant cell. Thus, as the plants continue growing for about another week, the gene transfer vectors combine the desirable features of the DNA mobilization plasmid, with gene control elements taken from single-stranded RNA plant viruses, to produce the encoded protein in abundance. With the target protein accumulated in the leaves, the plants are harvested, and the bulk drug substance is purified via traditional methods.

In the *FastPharming* System, no animal- or human-derived materials are used, decreasing the risk of product contamination with mammalian viruses or prions. In place of animal-origin raw materials, green plants, grown under clean and controlled conditions, provide for the expression of proteins. This portion of the bioprocess uses raw materials readily available to us, decreasing certain supply chain risks.

By incorporating transient gene expression technology, the *FastPharming* System can rapidly deliver high quality proteins for clinical use without several of the time-consuming steps that competitive mammalian-cell based expression systems require, such as the need to i) isolate a high-producing cell clone from millions of non-productive cells, ii) establish a master cell bank, and iii) grow the clonal cells in a sterile fermenter to start the manufacturing process. In addition to saving months of development time associated with traditional methods, the use of plants instead of bioreactors – and sterile liquid-handling systems to prevent bacterial, fungal, or viral contamination of the protein drug substance – saves money and reduces plastic waste.

FastPharming Facility Joint Venture with Eastern Capital Limited

iBio CDMO's operations take place in Bryan, Texas in a 130,000 square-foot cGMP manufacturing facility controlled by an affiliate (the "Second Eastern Affiliate") of Eastern Capital Limited ("Eastern"), a stockholder of the Company as sublandlord (the "Sublandlord"). The facility is a Class A life sciences building located on land owned by the Texas Agricultural and Mechanical College of Texas ("Texas A&M") system designed and equipped for the manufacture of plant-made biopharmaceuticals. The Sublandlord granted iBio CDMO a 34-year lease for the facility that expires in 2050.

On December 16, 2015, we formed iBio CDMO as a Delaware limited liability company to develop and manufacture plant-made pharmaceuticals. On January 13, 2016, we entered into a contract manufacturing joint venture with an affiliate of Eastern (the "Eastern Affiliate"). The Eastern Affiliate contributed $15 million in cash for a 30% interest in iBio CDMO. We retained a 70% interest in iBio CDMO and granted iBio CDMO a non-exclusive license to use our proprietary technologies for research purposes and an exclusive U.S. license for manufacturing purposes. We retained the exclusive right to grant product licenses to those who wish to sell or distribute products made using our technology. On February 23, 2017, we entered into an exchange agreement with the Eastern Affiliate, pursuant to which we acquired substantially all of the interest held by the Eastern Affiliate in iBio CDMO and issued one share of our iBio CMO Preferred Tracking Stock, par value $0.001 per share. After giving effect to the transaction, we own 99.99% of iBio CDMO. At any time, at our election or the election of the Eastern Affiliate, the outstanding share of iBio CMO Preferred Tracking Stock may be exchanged for 29,990,000 units of limited liability company interests of iBio CDMO. Following such exchange, we would own a 70% interest in iBio CDMO and the Eastern Affiliate would own a 30% interest.

See Notes 1, 13 and 14 in the consolidated financial statements for a further discussion.

Commercial activities commenced in January 2016 with most of our initial efforts directed towards recommissioning the facility to help meet cGMP manufacturing standards and provisions for iBio's service offerings. The facility houses laboratory and pilot-scale operations, as well as large-scale automated hydroponic systems capable of growing more than four million plants and delivering dozens of kilograms of protein per year.

Vaccines

In the first half of 2020, we renewed development of our E2 classic swine fever vaccine program (IBIO-400). During the second half of fiscal 2020, we entered the human vaccine space with the filing on March 11, 2020 of four provisional patent applications with the U.S. Patent and Trademark Office in support of our COVID-19 vaccine platforms, followed by the announcement in March 2020 of our Virus-Like Particle (VLP)-Based Platform ("VLP") vaccine program (IBIO-200) and our announcement in June 2020 of our second candidate, the *LicKM*-subunit vaccine (IBIO-201).

SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a strain of coronavirus that causes coronavirus disease 2019 (COVID-19). The virus was introduced to human populations from an animal source in the Chinese province of Hubei in late 2019. The spread of infection has since been driven by human-to-human transmission and has resulted in an ongoing pandemic. According to the World Health Organization, as of September 15, 2020, more than 28 million cases have been reported globally with more than 900,000 deaths.

IBIO-200

IBIO-200 is a vaccine candidate currently in preclinical development for the prevention of COVID-19 and leverages iBio's own VLP platform. The first VLP vaccine was approved in 1998, and the safety and effectiveness of additional VLP-based vaccines have been well documented since that time. VLP-based vaccines interact with immune cells differently than soluble antigens and trigger both humoral and cellular responses. IBIO-200 incorporates the receptor binding motif (RBM) of SARS-CoV-2 within the VLP structure to direct antigen presentation to activate both polyfunctional $CD4^+$ and $CD8^+$ T cells and increase the overall immune response. This design allows for a multivalent particle to display high density antigens to the immune system in a highly structured format. Combined with iBio's *FastPharming* Manufacturing System, iBio's technology delivers a tightly controlled particle size, leading to better dose definition and higher product consistency.

IBIO-201

IBIO-201 is a vaccine candidate currently in preclinical development for the prevention of COVID-19. IBIO-201 is based on a subunit platform that combines antigens derived from the SARS-CoV-2 spike protein fused with iBio's patented *LicKM*™ booster molecule to enhance immune response. iBio's proprietary *LicKM* technology offers the potential to strengthen the initial immune response to the antigen and extend the duration of the immune response.

Preclinical Development of IBIO-200 and IBIO-201

We have engaged in preclinical studies of both IBIO-200 and IBIO-201 and are developing IBIO-200 and IBIO-201 in tandem, and in combination with multiple adjuvants. In August 2020, we announced that preclinical immunization studies with IBIO-200 and IBIO-201, combined with select adjuvants from the Infectious Disease Research Institute ("IDRI"), induced anti-SARS-CoV-2 antibodies with notable antibody responses with two particular antigen-adjuvant combinations. Additional data from cell-based pseudovirus neutralization assay testing demonstrated that IBIO-201 induced the production of more anti-spike neutralizing antibodies than IBIO-200 in immunized mice. Based on these results, in September 2020, we announced the selection of IBIO-201 as our lead candidate for the prevention of SARS-CoV-2 infection. We intend to conduct more focused studies on each of IBIO-200 and IBIO-201 with the goal of advancing IBIO-201 to toxicology studies ahead of planned clinical development while we continue preclinical development of IBIO-200 and our VLP platform as a potential 'plug-and-play' vaccine development system.

Classical Swine Fever

Classical swine fever ("CSF") is a contagious, often fatal disease affecting both feral and domesticated pigs. Outbreaks in Europe, Asia, Africa, and South America have not only adversely impacted animal health and food security but have also had severe socioeconomic impacts on both the pig industry worldwide and small-scale pig farming.

IBIO-400

In collaboration with the Institute of Infectious Animal Diseases at Texas A&M University and Kansas State University, iBio used the *FastPharming* System to develop a potentially safe and protective [DIVA]-capable subunit vaccine. Characterized as a candidate that can "differentiate infected from vaccinated animals" [DIVA]-capable, the antigen is formulated in cost-effective oil-in-water emulsion adjuvants. IBIO-400 studies have shown that after single-dose vaccination, the adjuvanted, plant-made CSF E2 subunit vaccine provides complete protection in challenged pigs and is accompanied by strong virus neutralization antibody responses.

Therapeutics

We are developing novel therapeutic candidates that we believe can quickly move into clinical trials by using our*FastPharming*® System. Our current focus is on biological medicines for the treatment of fibrotic and infectious diseases, and we intend to continue to explore the application of our *FastPharming* Technologies in oncology and other therapeutic areas.

Fibrosis

Fibrosis is a pathological disorder in which connective tissue replaces normal parenchymal tissue to the extent that it goes unchecked, leading to considerable tissue remodeling and the formation of permanent scar tissue. Fibrosis can occur in many tissues within the body, including the lungs (e.g., idiopathic pulmonary fibrosis ("IPF") and skin (e.g. systemic scleroderma).

Systemic scleroderma is a rare chronic disease of uncertain etiology characterized by diffuse fibrosis and vascular abnormalities in the skin, joints, and internal organs. IPF is a type of chronic scarring lung disease characterized by a progressive and irreversible decline in lung function. In both cases, while there aremedications that can slow the progression of specific existing symptoms or temporarily reduce the development of new symptoms, there remains an unmet need for more effective treatments.

IBIO-100

IBIO-100, is our lead therapeutic candidate being advanced for Investigational New Drug ("IND") development based on in-licensed patents from the University of Pittsburgh. The molecule is a fusion of the endostatin derived E4 antifibrotic peptide to the hinge and heavy chain of human IgG1. In preclinical studies, IBIO-100 has been shown to reduce: (i) bleomycin-induced lung fibrosis in mice, as measured by hydroxyproline content and modified Ashcroft histopathology scoring; (ii) collagen content in mice in which fibrosis was produced by osmotic pump delivery of bleomycin followed by pump delivery of IBIO-100, and (iii) hydroxyproline content of human lung tissue obtained after transplant of diseased, terminal-stage organs. Tissue fragments exhibited a significant reduction of hydroxyproline when cultured in the presence of IBIO-100 after only 72 hours. We expect to conduct our remaining IND-enabling studies in 2021. IBIO-100 has been granted orphan drug designation by the FDA for treatment of systemic scleroderma.

COVID-19

Coronavirus disease 2019 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was first identified in December 2019 in Wuhan, Hubei, China, and has resulted in an ongoing pandemic. According to the World Health Organization, as of September 15, 2020, more than 28 million cases have been reported globally with more than 900,000 deaths. Common symptoms include fever, cough, fatigue, shortness of breath or breathing difficulties, and loss of smell and taste. While most people have mild symptoms, some people develop acute respiratory distress syndrome (ARDS), possibly precipitated by cytokine dysregulation, multi-organ failure, septic shock, and blood clots.

ACE2-Fc Immunoadhesin

As part of our strategy to develop new therapeutics for infectious diseases, we entered into an exclusive license agreement with Planet Biotechnology, Inc., ("Planet") in August 2020 to develop a recombinant ACE2-Fc protein as a treatment for COVID-19 and related coronavirus diseases. We received worldwide, sublicensable rights to the technology and assumed responsibility for preclinical development expenses. In the event we, at our sole discretion, choose to continue to develop the technology, Planet will be eligible for certain clinical development milestone payments, and royalties on net sales if products are commercialized. The molecule is in the lead optimization stage of development.

Research & Bioprocess Products

We are also developing recombinant proteins for third parties on a catalog and custom basis. We plan to initially focus on creating products that will help life science researchers working in the field of cell and tissue biofabrication, including those using 3D-bioprinting techniques. Biofabrication involves the use of cells, proteins, and biological materials to construct functional tissues and organs in the laboratory as a means to ultimately replace human donors as a source of organs for transplantation. The speed, economy, and safety profile of plant-produced recombinant proteins should allow us to leverage our *FastPharming* System to enter the market for cytokines, growth factors, scaffolds (sometimes referred to as "bioinks") and other proteins for use in the cell and tissue biofabrication category.

Strategic Alliances, Collaborations, and Service Agreements

We have formed collaborations and strategic alliances to gain access to funding, capabilities, technical resources and intellectual property to further our development efforts, commercialize our technology and to generate revenues, including through the development and manufacture of products at iBio's *FastPharming* Facility.

License Agreement with Planet Biotechnology, Inc.

As part of our strategy to develop new therapeutics for infectious diseases, we entered into an exclusive license agreement with Planet in August 2020, as described above.

Service Agreement with IBM, Corp.

In June 2020, we entered into a Cloud Services Agreement with IBM Watson Health under which iBio will receive free-of-charge access to IBM's clinical development solution for 18 months. Thereafter, we will be required to pay standard service fees.

Collaboration with AzarGen Biotechnologies (Pty) Ltd.

In March 2020, we entered into a second Statement of Work (SOW) with AzarGen Biotechnologies (Pty) Ltd ("AzarGen") under the 2018 Master Joint Development Agreement ("MJDA") between the companies. iBio continues to provide contract development and manufacturing services for AzarGen's development of a rituximab biosimilar/biobetter for the South African market.

Collaboration with The Texas A&M University System

We entered into two new SOWs with The Texas A&M University System ("TAMUS") during 2020. In March, we entered into an SOW related to iBio's preclinical development of COVID-19 vaccine candidates as part of the MJDA executed in June 2016. The other SOW, executed in January, involved TAMUS support of certain CDMO services.

License Agreement with University of Natural Resources and Life Sciences, Vienna

Effective February 1, 2020, we expanded our non-exclusive license agreement with the University of Natural Resources and Life Sciences, Vienna, to include commercial applications as well as research use of technology for the expression of recombinant proteins with modified N-glycosylation patterns in *Nicotiana benthamiana* plants.

Collaboration with EdgePoint AI, a division of Mateon Therapeutics, Inc.

On December 20, 2019, we entered into a collaboration agreement with EdgePoint AI, a division of Mateon Therapeutics, Inc., to deploy EdgePoint's proprietary artificial intelligence ("AI")/blockchain-driven vision system for pharmaceutical manufacturing, known as TrustPoint Fabric. Initial implementation is occurring at iBio's *FastPharming* Facility for the optimization of raw material documentation and verification activities from receipt through final manufacturing.

Collaboration with CC-Pharming Ltd.

In August 2019, we licensed our rituximab biosimilar/biobetter candidates to CC-Pharming Ltd. of Beijing ("CC-Pharming") for the China territory, along with a research license to the *FastPharming* Technologies for use in the evaluation of reagents for research, diagnostic, bioprocess, and cosmetic applications. The license to our rituximab candidate follows as part of the strategic, royalty-bearing, commercial relationship with we established with CC-Pharming in June 2018 under a MJDA between the parties. In April 2020, we amended and restated the Master Joint Development Agreement and iBio recognized more than $1.2 million in revenues in fiscal year 2020, primarily attributable to Process Development and Tech Transfer.

Service Agreement with Lung Biotechnology PBC, a subsidiary of United Therapeutics Corporation

In July 2019, we entered into an MSA with Lung Biotechnology PBC ("Lung Bio"), to produce recombinant human collagen ("rhCollagen") licensed from CollPlant Biotechnologies, Inc., to be used as a bioink for 3D bioprinting. The initial work involves the development of a scalable purification process for rhCollagen tailored to the biofabrication of lung scaffolds.

License with University of Pittsburgh ("UP")

On January 14, 2014 (the "Effective Date"), we entered into an exclusive worldwide License Agreement with UP covering all of the U.S. and foreign patents and patent applications and related intellectual property owned by UP pertinent to the use of endostatin peptides for the treatment of fibrosis. We paid an initial license fee of $20,000 and we are required to pay all of UP's patent prosecution costs that were incurred prior to, totaling $30,627, and subsequent to the Effective Date. On each anniversary date we are to pay license fees ranging from $25,000 to $150,000 for the first five years and $150,000 on each subsequent anniversary date until the first commercial sale of the licensed technology. Beginning with commercial sales of the technology or approval by the FDA or foreign equivalent, the Company will be required to pay milestone payments, royalties and a percentage of any non-royalty sublicense income to UP. We are also required to meet certain diligence milestones and we and UP have agreed to set a new milestone schedule and are currently undergoing an analysis based on new data and revised forecasted timelines.

Intellectual Property

We currently own or license 106 patents, of which 100 are owned and 6 are licensed. Of the 100 patents we own, 32 are U.S. and 68 are international. We have an exclusive license to five U.S. patents and one application. Additionally, we have one international patent application allowed, as well as seven U.S. and 12 international applications pending. International patents and applications include numerous foreign countries including Australia, Brazil, Canada, China, Hong Kong, India, Korea, Russia and several countries in Europe.

We exclusively own the right to use certain intellectual property acquired by or developed at Fraunhofer for human health and certain veterinary and diagnostic applications. We also own intellectual property developed or acquired independently of Fraunhofer.

In addition, we have an exclusive worldwide license agreement with the University of Pittsburgh covering U.S. and foreign patents and patent applications and related intellectual property co-owned with the University of Pittsburgh and the Medical University of South Carolina pertinent to the use of endostatin peptides for the treatment of fibrosis.

Our success will depend in part on our ability to obtain and maintain patent protection for our technologies and products and to preserve our trade secrets. Our policy is to seek to protect our proprietary rights, by among other methods, filing patent applications in the U.S. and foreign jurisdictions to cover certain aspects of our technology. We continue to prepare patent applications relating to our expanding technology in the U.S. and abroad.

The technology and products covered by our issued and pending patent applications are summarized below:

Technology and Product Patents (U.S.)

- Virus-induced gene silencing in plants
- Transient expression of foreign genes in plants
- Production of foreign nucleic acids and polypeptides in sprout systems
- Production of pharmaceutically active proteins in sprouted seedlings
- Systems and method for clonal expression in plants
- Recombinant carrier molecule for expression, delivery and purification of target polypeptides
- Influenza antigens, vaccine compositions, and related methods
- Plague antigens, vaccine compositions, and related methods
- Influenza therapeutic antibodies
- Trypanosomiasis vaccine
- Anthrax antigens, vaccine compositions, and related methods
- Use of endostatin peptides for the treatment of fibrosis

Pending Technology Patent Applications (U.S. and International)

- Activation of transgenes in plants by viral vectors
- Transient expression of proteins in plants
- Thermostable carrier molecule
- *In vivo* deglycosylation of recombinant proteins in plants

Pending Product Patent Applications (U.S. and International)

- Antibodies
- Influenza vaccines
- Influenza therapeutic antibodies
- Anthrax vaccines
- Plague vaccines
- HPV vaccines
- Trypanosomiasis vaccine
- Malaria vaccines
- Endostatin fragments and variants for use in treating fibrosis
- COVID-19 vaccines

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products.

We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we or our collaborators may develop based on the use of our technologies.

Our competition in the CDMO market includes a number of full-service contract manufacturers and large pharmaceutical companies offering third-party development and manufacturing services to fill their excess capacity. Large pharmaceutical companies have been seeking to divest portions of their manufacturing capacity, and any such divested businesses may compete with us in the future. In addition, most of our competitors may have substantially greater financial, marketing, technical or other resources than we do. Moreover, additional competition may emerge and may, among other things, result in a decrease in the fees paid for our services, which would affect our results of operations and financial condition.

While we believe that the potential advantages of our new technologies will enable us to compete effectively against other providers of technology for biologic product development and manufacturing, many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through arrangements with large and established companies, and this may reduce the value of our technologies for the purposes of establishing license agreements. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect to rely upon licensees, collaborators or customers for support in advancing certain of our drug candidates and intend to rely on additional work with our collaborators during our efforts to commercialize our product candidates. Our licensees, collaborators or customers may be conducting multiple product development efforts within the same disease areas that are the subjects of their agreements with us. Agreements with collaborators may not preclude them from pursuing development efforts using a different approach from that which is the subject of our agreement with them. Any of our drug candidates, therefore, may be subject to competition with a drug candidate under development by a customer.

There are currently approved vaccines and therapies for many of the diseases and conditions addressed by the product candidates our clients and collaborators may be developing or manufacturing or in our own pipeline. Specifically, with respect to the development of COVD-19 biopharmaceuticals, there are over 180 vaccines in various stages of development, and 549 therapeutics, according to the Biotechnology Industry Organization. Several of those candidates are in late stage clinical trials and are sponsored by large, multinational biopharmaceutical companies, some of whom have also received government funding. There are also a number of companies working to develop new drugs and other therapies for diseases of commercial interest to us that are undergoing various stages of testing including clinical trials. The key competitive factors affecting the success of our technologies for commercial product candidates are likely to be efficacy, safety profile, price, and convenience.

Research and Development

Our research and development functions are focused on the creation of new products and services, as well as enhancements to our existing offerings, both of which are necessary to maintain our competitive position. Our research and development activities take place primarily at our facilities in Bryan, Texas.

Suppliers

We outsource certain functions to third parties. While we rely on our outsourcing partners to perform their contracted functions, we are continuing to build internal capabilities. Refer to Item 1A, “Risk Factors,” for a description of risks associated with our reliance on suppliers and outsourcing partners.

Backlog

Our backlog consists primarily of orders for which we have entered into a Master Services Agreement with an accompanying Statement of Work (“SOW”). Our backlog was approximately $2.6 million as of June 30, 2020.

Government Regulation and Product Approval

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacturing and marketing of pharmaceutical drugs and vaccines.

CDMO Regulatory Requirements

iBio CDMO’s operations are subject to a variety of environmental, health and safety laws and regulations, including those of the Environmental Protection Agency and equivalent local and state agencies. These laws and regulations govern, among other things, air emissions, wastewater discharges, the use, handling and disposal of hazardous substances and wastes, soil and groundwater contamination and employee health and safety. Any failure to comply with environmental, health and safety requirements could result in the limitation or suspension of production or monetary fines or civil or criminal sanctions, or other future liabilities. iBio CDMO is also subject to laws and regulations governing the destruction and disposal of raw materials and the handling and disposal of regulated material. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with current Good Manufacturing Practices (“cGMPs”), labeling and distribution, import and export, and product registration and listing. As a result, our facility is subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions where our customers have marketing approval for their products.

Certain products manufactured by us involve the use, storage and transportation of toxic and hazardous materials. Our operations are subject to extensive laws and regulations relating to the storage, handling, emission, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities. Prevailing legislation tends to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

These regulatory requirements impact many aspects of our operations, including manufacturing, developing, labeling, packaging, storage, distribution, import and export and record keeping related to customers' products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve facilities for manufacturing products or products for commercialization.

U.S. Drug Approval Process

All of the vaccine and therapeutic products developed from our technologies will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical drugs and vaccines are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the U.S. Food and Drug Administration ("FDA") and regulatory authorities in other countries. In the U.S., various federal, and, in some cases, state statutes and regulations, also govern or impact the manufacturing, safety, labeling, storage, record-keeping and marketing of vaccines and pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations requires the expenditure of substantial resources. Regulatory approval, if and when obtained for any of our product candidates, may be limited in scope, which may significantly limit the indicated uses for which our product candidates may be marketed. Further, FDA approved vaccines and drugs are subject to ongoing oversight and discovery of previously unknown problems may result in restrictions on their manufacture, sale or use, or in their withdrawal from the market.
The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies according to good laboratory practices ("GLP") and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an Investigational New Drug ("IND") application which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("GCPs") and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a New Drug Application or NDA or Biologics License Application ("BLA") for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the NDA or BLA based on results of pre-clinical testing and clinical trials;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product candidates are produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- potential FDA audit of the pre-clinical trial and clinical trial sites that generated the data in support of the NDA or BLA; and

- FDA review and approval of the NDA or licensure of the BLA.

Before any product candidates with potential immunization or therapeutic value may be tested in human subjects, we must satisfy stringent government requirements for preclinical studies. Preclinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of the product candidate. "*In vitro*" refers to tests conducted with cells in culture and "*in vivo*" refers to tests conducted in animals. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory procedures ("GLP"). Preclinical testing results obtained from studies in several animal species, as well as data from *in vitro* studies, are submitted to the FDA as part of an IND application and are reviewed by the FDA prior to the commencement of human clinical trials. These preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical trials. In the case of vaccine candidates, animal immunogenicity and immune protection tests must establish a sound scientific basis to believe that the product candidate may be beneficial when administered to humans.

An IND becomes effective automatically 30 days after receipt by the FDA unless the FDA raises concern or questions about the conduct of the clinical trials as outlined in the IND prior to that time. In such an event, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may proceed. For additional information on the most recent FDA regulations and guidance on vaccine and therapeutic product testing and approval, visit its website at http://www.fda.gov. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to potential safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the good clinical practice requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials involving biological products are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biological product is initially introduced into a small number of closely monitored healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease.

- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. Clinical trials generally enroll a large number of volunteers and are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial FDA marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted.

U.S. Review and Approval Processes

After the completion of clinical trials of a product candidate, FDA approval of an NDA or BLA must be obtained before commercial marketing of the product. The NDA or BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee on approved biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews an NDA or BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA or BLA. The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe, potent, and effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve an NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the NDA or BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of Prescription Drug User Fee Act, or PDUFA, fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Fast Track Program

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For a Fast Track product, the FDA may consider review of completed sections of an NDA or BLA on a rolling basis provided the sponsor provides, and the FDA accepts, a schedule for the submission of the completed sections of the NDA or BLA. Under these circumstances, the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. A Fast Track designated drug candidate may also qualify for Priority Review designation, under which the FDA reviews the NDA or BLA in a total of six months rather than ten months after it is accepted for filing.

Post-Approval Requirements

Any products for which we receive FDA approvals will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA or NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's FDA approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, research, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of HIPAA, as amended by HITECH, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act., as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; making a false statement or record material to payment of a false claim; or avoiding, decreasing or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. Pharmaceutical and other healthcare companies have been prosecuted under these laws, for among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Pharmaceutical and other healthcare companies also have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and their respective implementing regulations, imposes requirements on covered entities, including health plans, health clearinghouses, and certain healthcare providers, and their business associates relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans, and healthcare clearinghouse, that create, receive, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in specified circumstances, some of which are more stringent and many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, (with certain exceptions), to annually report to the CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians, as defined by such law, and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. In addition, in order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost- effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidate for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. We expect that there will continue to be a number of federal and state proposals to implement government pricing controls and limit the grown of healthcare costs. For example, the ACA was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. There remain judicial and Congressional challenges to the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA were signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact our business in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. For example, it is possible that additional government action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Data Collection

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation 2016/679 ("GDPR"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for data controllers of personal data (including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements) and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects**.**

Employees

As of October 8, 2020, we had four employees in iBio and forty-seven employees in iBio CDMO, forty-three of which are full time employees. Our employees are not represented by any union and are not the subject of a collective bargaining agreement. We consider our relations with our employees to be good. We believe that we will need to continue to add staff during FY21 in order to meet our new growth objectives for Therapeutic, Vaccine, and Research & Bioprocess proprietary product development.

Corporate Information

We were incorporated under the laws of the State of Delaware on April 17, 2008 under the name iBioPharma, Inc. We engaged in a merger with InB:Biotechnologies, Inc., a New Jersey corporation on July 25, 2008 and changed our name to iBio, Inc. on August 10, 2009.

Available Information

Our website address is www.ibioinc.com. We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the Securities and Exchange Commission, or SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on our website at www.ibioinc.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors.

Our business faces many risks. Past experience may not be indicative of future performance, and as noted elsewhere in this Annual Report on Form 10-K, we have included forward-looking statements about our business, plans and prospects that are subject to change. Forward-looking statements are particularly located in, but not limited to, the sections "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In addition to the other risks or uncertainties contained in this Annual Report, the risks described below may affect our operating results, financial condition and cash flows. If any of these risks occur, either alone or in combination with other factors, our business, financial condition or operating results could be adversely affected and the trading price of our common stock may decline. Moreover, readers should note this is not an exhaustive list of the risks we face; some risks are unknown or not quantifiable, and other risks that we currently perceive as immaterial may ultimately prove more significant than expected. Statements about plans, predictions or expectations should not be construed to be assurances of performance or promises to take a given course of action.

COVID-19

We have in the past been impacted by the COVID-19 pandemic and may in the future been impacted by the COVID-19 pandemic

As a result of the pandemic, we have at times experienced reduced capacity to provide CDMO services as a result of instituting social distancing at work requirements in our Texas facility, restricting access to essential workers, as well as taking other precautions. We also experienced a full three-day operational shutdown in April 2020 for extensive facility cleaning following the discovery that an employee had contracted COVID-19, and successfully resumed operations on a reduced capacity basis.

We have ascertained that certain risks associated with further COVID-19 developments may adversely impact our operations and liquidity, and our business and share price may also be affected by the COVID-19 pandemic. However, we do not anticipate any significant threat to our operations at this point in time. Due to the general unknown nature surrounding the crisis, we cannot reasonably estimate the potential for any future impacts on our operations or liquidity.

The outbreak and spread of COVID-19 and continued progress in various countries around the world, including the United States, has led authorities around the globe to take various extraordinary measures to stem the spread of the disease, such as emergency travel and transportation restrictions, school closures, quarantines and social distancing measures. The outbreak of COVID-19 has had an adverse effect on global markets and may lead to a major slowdown in the economy in the United States and globally.

In recognition of the significant threat to the liquidity of financial markets posed by COVID-19, on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), a stimulus bill intended to bolster the U.S. economy, among other things, was signed into law to provide emergency assistance to qualifying businesses and individuals. There can be no assurance that these interventions by the government will be successful, and the financial markets may experience significant contractions in available liquidity. On April 16, 2020, the Company received $600,000 related to its filing under the Paycheck Protection Program and the CARES Act. Forgiveness of this loan is only available for principal that is used for the limited purposes that qualify for forgiveness under the Small Business Administration's ("SBA") requirements, and that to obtain forgiveness, we must request it and must provide documentation in accordance with the SBA's requirements, and certify that the amounts we are requesting to be forgiven qualify under those requirements. Forgiveness of the loan is dependent upon approval of the SBA and there can be no assurance or certainty that forgiveness will in fact occur. It is not possible at this time to estimate the further need, availability, extent or impact of any additional such relief. There can be no assurance that these interventions by the government will be successful, and the financial markets may experience significant contractions in available liquidity. Although the Company does not anticipate current operational difficulties, the risk exists that further COVID-19 developments may negatively impact the Company's financial condition and restrict the availability of liquidity for its operational needs.

On March 11, 2020, iBio filed four provisional patent applications (the "Patent Applications") that apply its Virus Like Particle ("VLP") platform technology, or its lichenase carrier immunostimulatory ("*LicKM*") adjuvant technology, in conjunction with its *FastPharming* Manufacturing System for treating or preventing infections with the SARS-CoV-2 virus, which is the agent that causes COVID-19. We announced our first proprietary COVID-19 development program on March 26, 2020, and its second program on June 4, 2020.

In addition, as previously announced, on February 6, 2020, iBio and CC-Pharming Ltd., of Beijing, China ("CC-Pharming") executed a Statement of Work 2 ("SOW2"), pursuant to an existing Master Joint Development Agreement to develop and test a new CC-Pharming SARS-CoV-2 antigen to be manufactured using iBio's *FastPharming* Manufacturing System. The contemplated collaborative effort has not yet progressed in any material respect.

There is no assurance that our activities relating to the development of intellectual property in the field of vaccine candidate development for the SARS-CoV-2 virus, which are reflected in the filing of the Patent Applications described above, will result in the development of any successful product candidates or generate any proceeds or that we will be able to develop a vaccine in time for its use. These efforts are subject to the risks relating to the development and commercialization of our technologies and product candidates, risks relating to our intellectual property and other risks relating to our operations described in this Annual Report.

In addition, we may face additional risks relating to the COVID-19 pandemic and its potential negative effects on our operations, share price and its toll on the world economy and health risks generally. COVID-19 may affect our operations and those of third parties on which we rely, including our customers and suppliers. Our business, financial condition, and results of operations may be affected by: disruptions in our customers' abilities to fund, develop, or bring to market products as anticipated; delays in or disruptions to the conduct of clinical trials by our customers; cancellations of contracts or confirmed orders from our customers; and the inability, difficulty, or additional cost or delays in obtaining key raw materials, components, and other supplies from our existing supply chain; among other factors caused by the COVID-19 pandemic. Our operations could again be disrupted if some of our employees become ill or are otherwise absent from work as a result of the COVID-19 pandemic. Additionally, governmental restrictions, including travel restrictions, quarantines, shelter-in-place orders, business closures, new safety requirements or regulations, or restrictions on the import or export of certain materials, or other operational issues related to the COVID-19 pandemic may have an adverse effect on our business and results of operations. We continue to monitor our operations and governmental recommendations and have made modifications for an indefinite period to our normal operations because of the COVID-19 pandemic, including requiring most non-production related employees to work remotely, which may increase cyber security risks or create data accessibility concerns.

The evolving nature of the circumstances is such that it is impossible, at this stage, to determine the full and overall impact the COVID-19 pandemic may have, but it could further disrupt production and cause delays in the supply and delivery of products used in our operations, adversely affect our employees and disrupt our operations and manufacturing activities, all of which may have a material adverse effect on our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses during our next fiscal year and may never achieve or maintain profitability.

Since our 2008 spinoff from Integrated BioPharma, we have incurred operating losses and negative cash flows from operations. Our net loss was approximately $16.4 million and $17.6 million for 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of approximately $150.4 million.

To date, we have financed our operations primarily through the sale of common stock, preferred stock and warrants. We have devoted substantially all of our efforts to research and development, including the development and validation of our technologies, our CDMO facilities, and the development of a proprietary therapeutic product against fibrosis and COVID-19 vaccines based upon our technologies. We have not completed development of or commercialized any vaccine or therapeutic product candidates. We expect to continue to incur significant expenses and may incur operating losses for at least the next year. We anticipate that our expenses and losses will increase substantially if we:

- initiate clinical trials of our product candidates;
- continue the research and development of our product candidates;
- seek to discover additional product candidates; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and manufacturing efforts.

To become and remain profitable, we must succeed in attracting and maintaining customers for the development, manufacturing and technology transfer services offered by iBio CDMO, or acquire customers for our new Research & Bioprocess Products presently in development. Our profitability in large part depends on the spending on iBio CDMO's services by its customers and potential customers and our ability to successfully develop and commercialize our product candidates. In addition, our profitability will also depend on continuing to commercialize our technologies or we, alone or with our licensees, must succeed in developing and eventually commercializing products that generate significant revenue. This will require us, alone or with our licensees and collaborators, to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which regulatory approval is obtained or establishing collaborations with parties willing and able to provide necessary capital or other value. We may never succeed in these activities. We may never generate revenues that are significant or large enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would diminish the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We anticipate that our expenses will increase in the future.

We expect our research and development expenses to increase significantly as our product candidates advance in clinical development. Because of numerous risks and uncertainties involved in our business, the timing or amount of increased development expenses cannot be accurately predicted, and our expenses could increase beyond expectations if we are required by the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidate is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for our product candidate. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. These losses have had and will continue to have an adverse effect on our financial position and working capital.

We anticipate that our expenses will increase to the extent we:

- continue the research and development of product candidates, and any future product candidates;
- conduct additional clinical studies of our product candidates in the future;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize our product candidates or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture our product candidates at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of our product candidate and any future product candidates and, if a product candidate is approved, our commercialization efforts.

We need additional funding to fully execute our business plan, which funding may not be available on commercially acceptable terms or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate the commercialization of our development and manufacturing services and efforts or our product development programs.

Even though we issued and sold an aggregate of (i) 19,473,013 shares of our common stock through July 16, 2020 for gross proceeds of $25,228,437 pursuant to the Lincoln Park March 2020 Purchase Agreement and (ii) 28,394,064 shares of our common stock September 9, 2020 for gross proceeds of $68,888,074 pursuant to the equity distribution agreement with UBS Securities, LLC ("UBS Securities") as our sales agent, as well as a significant percentage of the additional $27,000,000 of shares of our common stock pursuant to the equity distribution agreement, as amended by amendment no. 1, we still need additional capital to fully implement our current business, operating and development plans. To the extent that we initiate or continue clinical development without securing collaborator or licensee funding, our research and development expenses could increase substantially. Additionally, if we are unsuccessful in our efforts to attract and retain customers for CDMO services, develop and launch Research & Bioprocess Products, out-license our technologies and product candidates, or we find that it is necessary to advance the development of product candidates further than contemplated by our current business plans to secure favorable licensing terms, we would require substantial additional capital.

When we elect to raise additional funds or additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. In addition, no further sales of shares of our common stock will be made pursuant to the Purchase Agreement that we entered into with Lincoln Park in March 2020 since we could no longer issue additional shares due to NYSE American limitations and therefore we terminated such agreement, effective July 27, 2020. If we are unable to raise capital in sufficient amounts when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

Given that our total cash and marketable securities as of October 8, 2020, exceeded $83 million we believe we have adequate cash to support our current operations. We plan to fund our future business operations using cash on hand, through proceeds realized in connection with the commercialization of our technologies and proprietary products, license and collaboration arrangements and the operation of iBio CDMO, and through proceeds from the sale of additional equity or other securities. We cannot be certain that such funding will be available on favorable terms or available at all. To the extent that the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution.

We have based this projection on assumptions that may prove to be wrong, in which case we may deplete our cash resources sooner than we currently anticipate. Our future capital requirements will depend on many factors, including:

- further obtaining and retention of developmental, manufacturing and facility build-out and technology transfer opportunities at iBio CDMO;
- the ability to generate and increase third-party client sales and realized revenue at iBio CDMO;
- our ability to attract additional licensees or other third parties willing to fund development and, if successful, commercialization of product candidates;
- the costs, timing and regulatory review of our own product candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent to which we acquire or invest in businesses, products and technologies.

If we are unable to raise funds when required or on favorable terms, this assumption may no longer be operative, and we may have to: a) significantly delay, scale back, or discontinue the product application and/or commercialization of our proprietary technologies; b) seek collaborators for our technology and product candidates on terms that are less favorable than might otherwise be available; c) relinquish or otherwise dispose of rights to technologies, product candidates, or products that we would otherwise seek to develop or commercialize; or d) possibly cease operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time as we can generate substantial development, manufacturing, license or product revenues, we expect to finance our cash needs through a combination of equity offerings, collaborations, strategic alliances, service contracts, manufacturing contracts, facility build-out and technology transfer contracts, licensing and other arrangements. Sources of funds may not be available or, if available, may not be available on terms satisfactory to us.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

To the extent that we raise additional capital through a public or private offering and sale of equity securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

We have a limited operating history conducting commercial activities as a CDMO and developing vaccines and therapeutics, which may limit the ability of investors to make an informed investment decision.

We commenced independent operations in 2008, and our operations to date have included organizing and staffing our company, business planning, raising capital, acquiring and developing our proprietary technologies, recommissioning and operating our CDMO facility, identifying potential product candidates and undertaking, through third parties, preclinical trials and clinical trials of product candidates derived from our technologies. Commercial activities at our CDMO facility commenced in January 2016 with the large majority of our early efforts directed towards recommissioning the facility to help meet cGMP manufacturing standards and provisions for iBio's core service offerings. The current vaccines and therapeutics being developed are all in preclinical development. Certain vaccine candidates using iBio's technologies have previously been evaluated by other organizations in Phase 1 clinical trials; however, all of our vaccine and therapeutic protein product candidates are still in preclinical development. Neither we nor our collaborators have completed any other clinical trials for any vaccine or therapeutic protein product candidate produced using iBio technology. As a result, we have not yet demonstrated our ability to successfully complete any Phase 2 or pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any conclusion you reach about our future success or viability may not be as predictive as it might be if we had a longer operating history.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate significant revenue from such product candidates, if at all. Our ability to generate revenue depends on a number of factors, including our ability to:

- set an acceptable price for our products and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems; add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- manufacture commercial quantities of product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will generate significant revenue. If we cannot successfully execute on any of the factors listed above, our business may not succeed, and we may never generate significant revenue.

Reliance on government funding for our R&D programs may impose requirements that limit our ability to take certain actions, and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.

We have applied for government grants to support some of our research and development activities for our product candidates. Often government grants include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters.

Risks Related to the Development and Commercialization of Our Technologies and Product Candidates

We rely on licenses to use various technologies that are material to our business and if the agreements underlying the licenses were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

Our prospects for our fibrosis product candidate are significantly dependent upon our U-Pitt License Agreements. The license grants us exclusive, worldwide rights to certain existing patents and related intellectual property that cover fibrosis. If we breach the terms of the license, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones and by certain deadlines or other factors, U-Pitt has the right to terminate the license. If we were to lose or otherwise be unable to maintain the license on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market IBIO-100.

We currently have only four product candidates in early stages of pre-clinical development and are dependent on the success of these product candidates, which requires significant clinical testing before seeking regulatory approval. If our product candidates do not receive regulatory approval or are not successfully commercialized, our business may be harmed.

We are currently in preclinical development of four product candidates, IBIO-100, -200, -201 and -400, as a potential treatment for of fibrosis, COVID-19 and a veterinary vaccine for swine fever. It is possible that we may never be able to develop a marketable product candidate.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to these product candidates. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates, which may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of product candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any product in the United States unless and until we receive approval from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. We have never submitted an NDA or BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA or BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of its product for many reasons.

We depend on spending and demand from our customers for our contract manufacturing and development services.

Any reduction in customer spending on outsourcing contract manufacturing and development services could have a material adverse effect on our business, financial condition, and results of operations. The amount that our customers choose to spend on our contract manufacturing and development services offerings is based upon, among other things, the clinical outcomes and market success of their research, development and marketing, available resources, access to capital and their need to develop new products which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. In addition, increasing consolidation in the pharmaceutical industry may adversely impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations.

Our business, financial condition, and results of operations could be significantly impacted if the products we manufacture for our customers do not gain market acceptance.

If the products we manufacture for our customers do not gain market acceptance or production volumes of key products that we manufacture for our customers decline, our financial condition and results of operations may be adversely affected. We depend on, and have no control over, market acceptance for the products we manufacture for our customers. Consumer demand for our customers' products could be adversely affected by, among other things, delays in securing regulatory approvals, the emergence of competing or alternative products, including generic drugs, the loss of patent and other intellectual property rights protection, reductions in private and government payment product subsidies or changing product marketing strategies.

We expect that continued changes to the healthcare industry, including ongoing healthcare reform, changes in government or private funding of healthcare products and services, legislation or regulations governing the delivery, pricing or reimbursement of pharmaceuticals and healthcare services or mandated benefits, could cause healthcare industry participants to purchase fewer services from us or influence the price that others are willing to pay for our services. Changes in the healthcare industry's pricing, selling, inventory, distribution or supply policies or practices could also significantly reduce our revenue and profitability.

We may expend our limited resources to pursue a particular technology or product candidate and fail to capitalize on technologies or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates derived from or enhanced by our technologies or that have been identified and partially developed by our clients or collaborators. As a result, we may forego or delay pursuit of opportunities with other technologies or product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending and the spending of our clients and collaborators may not yield any commercially viable products.

We have based our research and development efforts largely on our technologies and product candidates derived from such technologies. Notwithstanding our large investment to date and anticipated future expenditures in these technologies, we have not yet developed, and may never successfully develop, any marketed products using these technologies. As a result, we may fail to address or develop product candidates based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

We also may not be successful in our efforts to identify or discover additional product candidates using our technologies. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements on terms less favorable to us than possible.

We, our clients and collaborators, are very early in our development efforts. If we or our clients and collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business will be materially harmed.

Excepting a limited number of vaccine candidates that have been evaluated in completed Phase 1 clinical trials, all of our other vaccine and therapeutic protein product candidates are still in preclinical development. Our ability to generate product sales revenues for our own products, which we do not expect will occur for many years, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, which may exceed patent exclusivity, for our product candidates;
- making arrangements with third-party manufacturers for commercial manufacturing capabilities;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- successfully maintaining existing collaborations and entering into new ones throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other products;

- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for any products we successfully develop;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business.

We may not be successful in our efforts to use iBio technologies to build a pipeline of product candidates and develop marketable products.

While we believe that data we and our collaborators have obtained from preclinical studies and Phase I clinical trials of iBio technology-derived and iBio technology-enhanced product candidates has validated these technologies, our technologies have not yet, and may never lead to, approvable or marketable products. Even if we are successful in further validating our technologies and continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development for many possible reasons, including harmful side effects, limited efficacy or other characteristics that indicate that such product candidates are unlikely to be products that will receive marketing approval and achieve market acceptance. If we and our collaborators do not successfully develop and commercialize product candidates based upon our technologies, we will not obtain product or collaboration revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Neither we nor our clients, collaborators or licensees will be able to commercialize product candidates based on our technologies and services if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans.

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. We and our licensees may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent the commercialization of product candidates based on our iBio technologies, including the following:

- Preclinical or clinical trials may produce negative or inconclusive results, which may require additional preclinical testing, additional clinical trials or the abandonment of projects that we expect to be promising. For example, promising animal data may be obtained about the anticipated efficacy of a therapeutic protein product candidate and then human tests may not result in such an effect. In addition, unexpected safety concerns may be encountered that would require further testing even if the therapeutic protein product candidate produced an otherwise favorable response in human subjects.
- Initial clinical results may not be supported by further or more extensive clinical trials. For example, a licensee may obtain data that suggest a desirable immune response from a vaccine candidate in a small human study, but when tests are conducted on larger numbers of people, the same extent of immune response may not occur. If the immune response generated by a vaccine is too low or occurs in too few treated individuals, then the vaccine will have no commercial value.
- Enrollment in our or our licensee's clinical trials may be slower than projected, resulting in significant delays. The cost of conducting a clinical trial increases as the time required to enroll adequate numbers of human subjects to obtain meaningful results increases. Enrollment in a clinical trial can be a slower-than-anticipated process because of competition from other clinical trials, because the study is not of interest to qualified subjects, or because the stringency of requirements for enrollment limits the number of people who are eligible to participate in the clinical trial.
- We or our licensees might have to suspend or terminate clinical trials if the participating subjects are being exposed to unacceptable health risks. Animal tests do not always adequately predict potential safety risks to human subjects. The risk of any candidate product is unknown until it is tested in human subjects, and if subjects experience adverse events during the clinical trial, the trial may have to be suspended and modified or terminated entirely.
- Regulators or institutional review boards may suspend or terminate clinical research for various reasons, including safety concerns or noncompliance with regulatory requirements.
- Any regulatory approval ultimately obtained may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable.

- The effects of iBio technology-derived or iBio technology-enhanced product candidates may not be the desired effects or may include undesirable side effects.

Significant clinical trial delays could allow our competitors to bring products to market before we or our licensees do and impair our ability to commercialize our technologies and product candidates based on our technologies. Poor clinical trial results or delays may make it impossible to license a product candidate, or reduce its attractiveness to prospective licensees, so that we will be unable to successfully develop and commercialize such a product candidate.

Clinical trials are risky, lengthy and expensive. We incur substantial expense for, and devote significant time and resources to, preclinical testing and clinical trials, yet cannot be certain that these tests and trials will demonstrate that a product candidate is effective and well-tolerated, or will ever support its approval and commercial sale. For example, clinical trials require adequate supplies of clinical trial material and sufficient patient enrollment to power the trial. Delays in patient enrollment can result in increased costs and longer development times. Even if we, or a licensee or collaborator, if applicable, successfully complete clinical trials for our clinical product candidate, we or they might not file the required regulatory submissions in a timely manner and may not receive marketing approval for the clinical product candidate. We cannot assure you that our clinical product candidate will successfully progress further through the drug development process, or will ultimately result in an approved and commercially viable product.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of our clinical product candidate may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the trial drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the trial.

Furthermore, any negative results we may report in clinical trials of our clinical product candidate or negative results of similar product candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same clinical product candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on its ability to develop its clinical product candidate, or could render further development impossible. In addition, we expect to rely on contract research organizations ("CROs") and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing our services, we will be limited in our ability to compel our actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

If we, or our clients and collaborators, are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we, or our clients and collaborators, will not be able to commercialize our, or third-party, product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use in such a restrictive manner that it is not possible to obtain commercial viability for such product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years. If additional clinical trials are required for certain jurisdictions, these trials can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, and may ultimately be unsuccessful. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application, may cause delays in the review and approval of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application as deficient or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Although the FDA and other regulatory authorities have approved plant-based therapeutics in the past, consistent with the oversight of all products, the FDA is monitoring whether these plant-based therapeutics pose any health and human safety risks. While they have not issued any regulation to date that is averse to plant-based vaccines or therapeutics, it is possible that the FDA and other regulatory authorities could issue regulations in the future that could adversely affect our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Alternative technologies may supersede our technologies or make them noncompetitive, which would harm our ability to generate future revenue.

The manufacture of biologics and the methods of such manufacture are intensely competitive fields. Each of these fields is characterized by extensive research efforts, which result in rapid technological progress that can render existing technologies obsolete or economically noncompetitive. If our competitors succeed in developing more effective technologies or render our technologies obsolete or noncompetitive, our business will suffer. Many universities, public agencies and established pharmaceutical, biotechnology, and other life sciences companies with substantially greater resources than we have are developing and using technologies and are actively engaging in the development of products similar to or competitive with our technologies and products. To remain competitive, we must continue to invest in new technologies and improve existing technologies. To make such renewing investment we will need to obtain additional financing. If we are unable to secure such financing, we will not have sufficient resources to continue such investment. In addition, they also have significantly greater experience in the discovery and development of products, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Our competitors may devise methods and processes for protein expression that are faster, more efficient or less costly than that which can be achieved using iBio technologies. There has been and continues to be substantial academic and commercial research effort devoted to the development of such methods and processes. If successful competitive methods are developed, it may undermine the commercial basis for iBio products and our technologies and related services.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize product candidates that are superior to other products in the market;
- demonstrate through our clinical trials that our clinical product candidate is differentiated from existing and future therapies;
- attract qualified scientific and commercial personnel;
- obtain patent or other proprietary protection for its clinical product candidate;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new product candidates.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced therapies would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidate less competitive. In addition, any new products that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

Our clinical product candidate may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude its development or regulatory approval, or limit its use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our clinical product candidate in order to obtain regulatory approval to further advance our clinical development, or to eventually market it. Even if our clinical product candidate demonstrates adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our clinical product candidate, which could result in the delay or termination of its development, prevent regulatory approval, or limit its market acceptance if it is ultimately approved.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our clinical product candidate in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market our clinical product candidate in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our clinical product candidate in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and it does not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product candidate we develop will be unrealized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our clinical product candidate may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval. If our clinical product candidate receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of our clinical product candidate. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our clinical product candidate for its approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our clinical product candidate, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such clinical product candidate;
- restrictions on the labeling or marketing of such clinical product candidate;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the clinical product candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such clinical product candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such clinical product candidate;

- clinical product candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our clinical product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if our clinical product candidate receives marketing approval, we may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our clinical product candidate receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If we do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our clinical product candidate for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our product candidate option in addition to or in the place of our clinical product candidate;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our clinical product candidate to be based on the same mechanism of action, the failure of our first product candidate to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we otherwise planned.

The insurance coverage and reimbursement status of newly approved products are uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our clinical product candidate that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our clinical product candidate will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our clinical product candidate. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow it to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our clinical product candidate on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our clinical product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that it is able to charge for its clinical product candidate. Accordingly, in markets outside the United States, the reimbursement for its products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for its clinical product candidate. We expect to experience pricing pressures in connection with the sale of our clinical product candidate due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected for new products entering the marketplace.

Failure to comply with existing and future regulatory requirements could adversely affect our business, financial condition, and results of operations.

Our CDMO operations are highly regulated and we must comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities in which we manufacture products or in which our customers' products are distributed. In particular, we are subject to laws and regulations concerning development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, import and export, and product registration and listing, among other things. As a result, our facility is subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions where our customers have marketing approval for their products. As we expand our operations and geographic scope, we may be exposed to more complex and newer regulatory and administrative requirements and legal risks, any of which may require expertise in which we have little or no experience. It is possible that compliance with new regulatory requirements could impose significant compliance costs on us. Such costs could have a material adverse effect on our business, financial condition and results of operations.

Not only will our customers' products be subject to the regulatory approvals discussed above that our proprietary products will be subject to, but our facility is subject to governmental approval for the testing or manufacturing of products If our manufacturing facility is not able to demonstrate compliance with cGMPs, pass other aspects of pre-approval inspections or properly scale up to produce commercial supplies, the FDA or other regulatory agencies can delay approval of a customers' drug candidate.

In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards. This may require a change in our development and manufacturing techniques or additional capital investments in our facility. Any related costs may be significant. If we fail to comply with applicable regulatory requirements in the future, then we may be subject to warning letters and/or civil or criminal penalties and fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, restrictions on the import and export of our products, debarment, exclusion, disgorgement of profits, operating restrictions and criminal prosecution and the loss of contracts and resulting revenue losses. Inspections by regulatory authorities that identify any deficiencies could result in remedial actions, production stoppages or facility closure, which would disrupt the manufacturing process and supply of product to our customers. In addition, such failure to comply could expose us to contractual and product liability claims, including claims by customers for reimbursement for lost or damaged active pharmaceutical ingredients or recall or other corrective actions, the cost of which could be significant.

The FDA and comparable government authorities having jurisdiction in the countries in which we or our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product we manufacture is adulterated or misbranded. If our manufacturing facilities and services are not in compliance with the FDA and comparable government authorities, we may be unable to obtain or maintain the necessary approvals to continue manufacturing products for our customers, which would materially adversely affect our financial condition and results of operations.

Our customers' failure to receive or maintain regulatory approval for their product candidates could negatively impact our revenue and profitability.

Our contract manufacturing business materially depends upon the regulatory approval of the products we manufacture. As such, if our customers experience a delay in, or failure to receive, approval for any of their product candidates or fail to maintain regulatory approval of their products, our revenue and profitability could be adversely affected. Additionally, if the FDA or a comparable foreign regulatory authority does not approve of our facilities for the manufacture of a customer product or if it withdraws such approval in the future, our customers may choose to identify alternative manufacturing facilities and/or relationships, which could significantly impact our ability to expand our CDMO capacity and capabilities and achieve profitability.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers which, in turn, could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possible termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of its operations, any of which could harm our business.

Although we do not intend to provide healthcare services or submit claims for third party reimbursement, we will be subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal false claims act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;

- HIPAA, as amended by the HITECH Act, and their respective implementing regulations, imposes requirements on covered entities, including health plans, health clearinghouses, and certain health care providers, and their business associates relating to the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and other investment interests held by such professionals and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the ACA, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Any violations of these aforementioned laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in the imposition of significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, any of which could cause a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these or other transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has continued to result in a number of investigations, prosecutions, convictions and significant settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on its business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face the risk of product liability exposure in connection with the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;

- substantial monetary awards to trial participants or patients;

- loss of revenue;

- reduced resources of our management to pursue our business strategy; and

- the inability to commercialize any products that we may develop.

Prior to commencing human clinical trials, we will seek to obtain product liability insurance coverage. Such insurance coverage is expensive and may not be available in coverage amounts we seek or at all. If we obtain such coverage, we may in the future be unable to maintain such coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our clinical product candidate, if approved.

We do not have any infrastructure for the sales, marketing or distribution of our clinical product candidates, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product candidate that may be approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product candidate for which we have obtained marketing approval, we will need a sales and marketing organization. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. If we were to determine to develop our own sales organization, any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product candidate launch, which would adversely impact commercialization.

Factors that may inhibit our efforts to commercialize our clinical product candidate on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our products; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of our clinical product candidate, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our clinical product candidate outside the United States, we may be forced to delay the potential commercialization or reduce the scope of our sales or marketing activities. We may have to enter into arrangements with third parties or otherwise at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize our clinical product candidate outside of the United States, a variety of risks associated with international operations could harm our business.

If our clinical product candidate is approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;

- reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign reimbursement, pricing and insurance regimes;

- foreign taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- product shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our clinical product candidate and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of executive, legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our clinical product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There remain executive, judicial and Congressional challenges. Since January2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA were signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our clinical product candidate or additional pricing pressures. For example, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

For our clinical product candidates, we intend to use our own manufacturing facility. Any manufacturing problems experienced by us could result in a delay or interruption in the supply of our clinical product candidate until the problem is cured or until we locate and qualify an alternative source of manufacturing and supply.

We currently manufacture our clinical product candidates and do not have a second alternative manufacturer. If we were to experience any prolonged disruption for our manufacturing, we could be forced to seek additional third-party manufacturing contracts, thereby increasing our development costs and negatively impacting our timelines and any commercialization costs. If we change manufacturers at any point during the development process or after approval of a product candidate, we will be required to demonstrate comparability between the product manufactured by the old manufacturer and the product manufactured by the new manufacturer. If we are unable to do so we may need to conduct additional clinical trials with product manufactured by the new manufacturer.

If we are not able to manufacture sufficient quantities of our clinical product candidate, our development activities would be impaired. In addition, the manufacturing facility where our clinical product candidate is manufactured is subject to ongoing, periodic inspection by the FDA or other comparable regulatory agencies to ensure compliance with current Good Manufacturing Practice, or cGMP. Any failure to follow and document the manufacturer's adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of clinical bulk drug substance and finished product for clinical trials, which may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our clinical product candidate. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our clinical product candidate;
- being unable to increase the scale of or the capacity for, or reformulate the form of our clinical product candidate, which may cause us to experience a shortage in supply, or cause the cost to manufacture our clinical product candidate to increase.
- we cannot assure you that we will be able to manufacture our clinical product candidate at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- our facility closed as a result of regulatory sanctions, pandemic or a natural disaster;
- shortages of qualified personnel, raw materials or key contractors;
- failing to obtain FDA approval for commercial scale manufacturing; and
- ongoing compliance with cGMP regulations and other requirements of the FDA or other comparable regulatory agencies.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing is not economically feasible or we cannot find another third-party manufacturer, we may not be able to produce our clinical product candidate in a sufficient quantity to meet future demand.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If demand for our products materializes, we may have to invest additional resources to purchase materials, hire and train employees, and enhance our manufacturing processes. It may not be possible for us to manufacture our clinical product candidate at a cost or in quantities sufficient to make its clinical product candidate commercially viable. Any of these factors may affect our ability to manufacture our products and could reduce gross margins and profitability.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufacture our clinical product candidate ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If we rely on a third party contract manufacturer or its suppliers fail to deliver the required commercial quantities of our clinical product candidate required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our clinical product candidate and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our clinical product candidate, cause it to incur higher costs and could prevent us from commercializing our clinical product candidate successfully.

Risks Related to Dependence on Third Parties

Establishing and maintaining collaborations is a key component of our business strategy. If we are unable to establish new collaborations and maintain both new and existing collaborations, or if these collaborations are not successful, our business could be adversely affected.

Our current business plan contemplates that we will in the future derive significant revenues from collaborators and licensees that successfully utilize iBio technologies in connection with the production, development and commercialization of vaccines and therapeutic protein product candidates. Our realization of these revenues and dependence on existing collaborations, and any future collaborations we enter into, is subject to a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and, if successful, commercialization of product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products; or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we would potentially lose the right to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our technology and use this knowledge to compete with us in the future;
- results of collaborators' preclinical or clinical studies could produce results that harm or impair other products using our technology;
- there may be conflicts between different collaborators that could negatively affect those collaborations and others; and
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers.

If our collaborations do not result in the successful development and commercialization of products or if one or more of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed and we may need additional resources to develop additional product candidates. There can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

We seek to establish and collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of iBio technology-produced and iBio technology-enhanced product candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration depends, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we fail to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development or the development of one or more of our other product candidates, or increase our expenditures and undertake additional development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all.

If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product portfolio and our business may be materially and adversely affected.

If third parties on whom we or our licensees will rely for the conduct of preclinical studies and clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business may suffer.

We do not have the ability to independently conduct the preclinical studies and clinical trials required to obtain regulatory approval for our product candidates. We have not yet contracted with any third parties to conduct clinical trials of product candidates we develop independently of collaborators. We will depend on licensees or on independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical trials of our product candidates. We will rely heavily on these parties for successful execution of our clinical trials but will not control many aspects of their activities. For example, the investigators participating in our clinical trials will not be our employees. However, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

If revenue from a third-party customer or client is concentrated in an amount that makes up a significant percentage of our total revenues, we may be adversely impacted by the significant dependence upon that client, including but not limited to, receipt and collections of outstanding amounts, continued operational allocations toward the client and related efficiencies, capacity and opportunity costs.

At this time, we are continually promoting our technologies and CDMO capabilities to further expand and grow our revenue base and business. We will continue to consider any potential revenue and client related concentration risks. During the fiscal year ended June 30, 2020, CC-Pharming accounted for approximately 77% of total revenue. During the fiscal year ended June 30, 2019, CC-Pharming accounted for approximately 92% of our total revenues. Although we expect our revenues to increase significantly and further vary by client over the next twelve months, there are no guarantees we will be correct in our assumptions.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including CROs, consultants and principal investigators to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies and will rely on them for the recruitment of sites and subjects for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our clinical product candidate may be delayed or prove unsuccessful.

Further, the FDA, the EMA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to good clinical practices, or GCPs, or similar regulations. If we or a regulatory authority determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We will rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We will rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develops. As a result, our financial results and the commercial prospects for any product candidate that it develops would be harmed, its costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Our clinical product candidates may cause adverse effects or have other properties that could delay or prevent our regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our clinical product candidates or generally by plant-based therapeutics could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for our clinical product candidates, our ability to obtain regulatory approval for such clinical product candidate may be negatively impacted. In addition, adverse events caused by any clinical product candidate administered in combination with our product candidates could cause similar interruptions and delays, even though not caused by our clinical product candidates.

Furthermore, if any of our products are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the clinical product candidate or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could elect to discontinue the sale of the clinical product candidate; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected clinical product candidate and could substantially increase the costs of commercialization.

We rely on third parties to supply most of the necessary raw materials and supplies for the products we manufacture on behalf of our customers and our inability to obtain such raw materials or supplies may adversely impact our business, financial condition, and results of operations.

Our operations require various raw materials, including proprietary resins, buffers, and filters, in addition to numerous additional raw materials supplied primarily by third parties. We or our customers specify the raw materials and other items required to manufacture their product and, in some cases, specify the suppliers from whom we must purchase these raw materials. In certain instances, the raw materials and other items can only be supplied by a limited number of suppliers and, in some cases, a single source, or in limited quantities. If third-party suppliers do not supply raw materials or other items on a timely basis, it may cause a manufacturing run to be delayed or canceled which would adversely impact our financial condition and results of operations. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, cGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. If our primary suppliers become unable or unwilling to perform, any resulting delays or interruptions in the supply of raw materials required to support our manufacturing of cGMP pharmaceutical-grade products would ultimately delay our manufacture of products for our customers, which could materially and adversely affect our financial condition and operating results.

Furthermore, third-party suppliers may fail to provide us with raw materials and other items that meet the qualifications and specifications required by us or our customers. If third-party suppliers are not able to provide us with raw materials that meet our or our customers' specifications on a timely basis, we may be unable to manufacture their product or it could prevent us from delivering products to our customers within required timeframes. Any such delay in delivering our products may create liability for us to our customers for breach of contract or cause us to experience order cancellations and loss of customers. In the event that we manufacture products with inferior quality components and raw materials, we may become subject to product liability claims caused by defective raw materials or components from a third-party supplier or from a customer, or our customer may be required to recall its products from the market.

Any claims beyond our insurance coverage limits, or that are otherwise not covered by our insurance, may result in substantial costs and a reduction in our available capital resources.

We maintain property insurance, employer's liability insurance, product liability insurance, general liability insurance, business interruption insurance, and directors' and officers' liability insurance, among others. Although we maintain what we believe to be adequate insurance coverage, potential claims may exceed the amount of insurance coverage or may be excluded under the terms of the policy, which could cause an adverse effect on our business, financial condition and results from operations. Generally, we would be at risk for the loss of inventory that is not within customer specifications. These amounts could be significant. In addition, in the future we may not be able to obtain adequate insurance coverage or we may be required to pay higher premiums and accept higher deductibles in order to secure adequate insurance coverage.

We may be subject to various litigation claims and legal proceedings.

We, as well as certain of our directors and officers, may be subject to claims or lawsuits during the ordinary course of business. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted.

Risks Related to Intellectual Property

If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. PTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our pending or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us and our collaborators.

In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, products or use of our products do not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering our products or technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. PTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our limited number of personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are found to have failed to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are a party to an exclusive license agreement with Planet Biotechnology, Inc., an exclusive license agreement with University of Pittsburgh, as well as a non-exclusive license agreement with the University of Natural Resources and Life Sciences, Vienna, and may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our lead products or other product candidates that we may identify. Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization, and other obligations on us. In spite of our efforts, our licensors might allege that we have materially breached our obligations under such license agreements and might therefore attempt to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of our lead products or other product candidates that we may identify. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to protect our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license;
- our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application;
- our licensors or collaborators might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;
- pending patent applications may not lead to issued patents;
- issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

— We may choose not to file a patent application for certain trade secrets or know-how, and a third party may subsequently obtain a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employers. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing

of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Risks Related to iBio CDMO's Operations

If iBio CDMO is unable to provide quality and timely offerings to its customers, its business could suffer, which could have a material adverse impact on our business and results of operations.

A failure of quality control systems in iBio CDMO's facilities could cause problems to arise in connection with facility operations or during preparation or provision of products, in both cases, for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors. Such problems could affect production of a particular batch or series of batches, requiring the destruction of products, or could halt facility production altogether. In addition, failure to meet required quality standards may result in failure to timely deliver products to customers. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before a product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

A failure by iBio CDMO to attract and maintain customers and any reduction in spending or demand for iBio CDMO's development, manufacturing and technology transfer services could have a material adverse effect on our business.

iBio CDMO's operations will depend, in part, on its ability to attract and maintain customers for its development, manufacturing and technology transfer services and on the amount of customer spending on such services. If iBio CDMO fails to attract customers or its customers' and potential customers' spending on iBio CDMO's services is reduced, this may have a material adverse effect on our business, results of operations and financial condition.

iBio CDMO's operations are subject to environmental, health and safety laws and regulations, which could increase costs and restrict operations in the future.

iBio CDMO's operations are subject to a variety of environmental, health and safety laws and regulations, including those of the Environmental Protection Agency and equivalent local and state agencies. These laws and regulations govern, among other things, air emissions, wastewater discharges, the use, handling and disposal of hazardous substances and wastes, soil and groundwater contamination and employee health and safety. Any failure to comply with environmental, health and safety requirements could result in the limitation or suspension of production or monetary fines or civil or criminal sanctions, or other future liabilities. iBio CDMO is also subject to laws and regulations governing the destruction and disposal of raw materials and the handling and disposal of regulated material.

Our operating results will be adversely affected if we are unable to maximize our facility capacity utilization.

iBio CDMO's operating results are significantly influenced by our capacity utilization and, as such, if we are unable to utilize our facilities to capacity, our margins could be adversely affected, and our results of operations and financial condition will continue to be adversely affected. Further, while we continue to implement and execute our business plan and attract and maintain customers for our development, manufacturing and technology transfer services, our revenue volume may be insufficient to ensure the economical operation of our facilities, in which case our results of operations could be adversely affected.

A failure by iBio CDMO to hire and retain an appropriately skilled and adequate workforce could adversely impact the ability of the facility to operate and function efficiently.

iBio CDMO's operations will depend, in part, on its ability to attract and retain an appropriately skilled and sufficient workforce to operate its development and manufacturing facility. The facility is located in a growing biotechnology hub and competition for skilled workers will continue to increase as the industry undergoes further growth in the area.

Failure to comply with existing and future regulatory requirements could adversely affect our business, results of operations and financial condition.

Our industry is highly regulated. We are required to comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities in which we manufacture products or in which our customers' products are distributed. In particular, we are subject to laws and regulations concerning development, testing, manufacturing processes, equipment and facilities, including compliance with cGMP, import and export, and product registration and listing, among other things. As we expand our operations and geographic scope, we may be exposed to new and more complex regulatory and administrative requirements and legal risks, any of which may require expertise in which we have little or no experience. It is possible that compliance with new regulatory requirements could impose significant compliance costs on us. Such costs could have a material adverse effect on our business, financial condition and results of operations.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.

The amount that our customers spend on the development and manufacturing of their products or product candidates, particularly the amount our customers choose to spend on outsourcing these services to us, substantially impacts our revenue and profitability. The outcomes of our customers' research, development and marketing also significantly influence the amount that our customers choose to spend on our services and offerings. Our customers determine the amounts that they will spend on our services based upon, among other things, the clinical and market success of their products, available resources, access to capital and their need to develop new products, which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. Further, increasing consolidation in the pharmaceutical industry may impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations. Any reduction in customer spending on biologics development and related services as a result of these and other factors could have a material adverse effect on our business, results of operations and financial condition.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We intend to grow our business operations as demand increases and increase the number of our employees to accommodate such potential growth, which may cause us to experience periods of rapid growth and expansion. This potential future growth could create a strain on our organizational, administrative and operational infrastructure, including manufacturing operations, quality control, technical support and other administrative functions. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls.

As our commercial operations and sales volume grow, we will need to continue to increase our capacity for manufacturing, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. We may also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our manufacturing, maintenance, software and computing capacity to meet increased demand. These increases in scale, expansion of personnel, purchase of equipment or process enhancements may not be successfully implemented.

If we are unable to protect the confidentiality of our customers' proprietary information, we may be subject to claims.

Many of the formulations used and processes developed by us in manufacturing our customers' products are subject to trade secret protection, patents or other intellectual property protections owned or licensed by such customer. While we make significant efforts to protect our customers' proprietary and confidential information, including requiring our employees to enter into agreements protecting such information, if any of our employees breaches the non-disclosure provisions in such agreements, or if our customers make claims that their proprietary information has been disclosed, our reputation may suffer damage and we may become subject to legal proceedings that could require us to incur significant expenses and divert our management's time, attention and resources.

Our services and our customers' products may infringe on or misappropriate the intellectual property rights of third parties.

Any claims that our services infringe the rights of third parties, including claims arising from any of our customer engagements, regardless of their merit or resolution, could be costly and may divert the efforts and attention of our management and technical personnel. We may not prevail in such proceedings given the complex technical issues and inherent uncertainties in intellectual property litigation. If such proceedings result in an adverse outcome, we could be required, among other things, to pay substantial damages, discontinue the use of the infringing technology, expend significant resources to develop non-infringing technology, license such technology from the third party claiming infringement (which license may not be available on commercially reasonable terms or at all) and/or cease the manufacture, use or sale of the infringing processes or offerings, any of which could have a material adverse effect on our business.

In addition, our customers' products may be subject to claims of intellectual property infringement and such claims could materially affect our business if their products cease to be manufactured and they have to discontinue the use of the infringing technology which we may provide. Any of the foregoing could affect our ability to compete or could have a material adverse effect on our business, financial condition and results of operations.

If we do not enhance our existing or introduce new service offerings in a timely manner, our offerings may become obsolete or uncompetitive over time, customers may not buy our offerings and our revenue and profitability may decline.

iBio CDMO core services consist of the following offerings:

- Process Development
- Manufacturing
- Fill / Finish
- BioAnalytics
- Factory Solutions

Demand for any of our service offerings may change in ways that we may not anticipate due to evolving industry standards and customer needs that are increasingly sophisticated and varied, as well as the introduction by others of new offerings and technologies that provide alternatives to our offerings. In the event we are unable to offer or enhance our service offerings or expand our manufacturing infrastructure to accommodate requests from our customers and potential customers, our offerings may become obsolete or uncompetitive over time, in which case our revenue and operating results would suffer. For example, if we are unable to respond to changes in the nature or extent of the technological or other needs of our customers through enhancing our offerings, our competition may develop offerings that are more competitive than ours and we could find it more difficult to renew or expand existing agreements or obtain new agreements. Potential innovations intended to facilitate enhanced or new offerings generally will require a substantial capital investment before we can determine their commercial viability, and we may not have financial resources sufficient to fund all desired innovations. Even if we succeed in creating enhanced or new offerings, however, they may still fail to result in commercially successful offerings or may not produce revenue in excess of our costs of development, and they may be rendered obsolete by changing customer preferences or the introduction by our competitors of offerings embodying new technologies or features. Finally, the marketplace may not accept our innovations due to, among other things, existing patterns of clinical practice, the need for regulatory clearance and/or uncertainty over market access or government or third-party reimbursement.

Revenue amounts generated by iBio CDMO have corresponding percentage rent expense components with minimum amounts due which may adversely impact the Company's financial position and liquidity as we undergo business development and growth.

In addition to the base rent, iBio CDMO is required to pay to the Second Eastern Affiliate, for each calendar year during the term, a portion of the total gross sales for products manufactured or processed at the facility, equal to 7% of the first $5,000,000 of gross sales, 6% of gross sales between $5,000,001 and $25,000,000, 5% of gross sales between $25,000,001 and $50,000,000, 4% of gross sales between $50,000,001 and $100,000,000, and 3% of gross sales between $100,000,001 and $500,000,000. However, if for any calendar year period from January 1, 2018 through December 31, 2019, iBio CDMO's applicable gross sales are less than $5,000,000, or for any calendar year period from and after January 1, 2020, its applicable gross sales are less than $10,000,000, then iBio CDMO is required to pay the amount that would have been payable if it had achieved such minimum gross sales and shall pay no less than the applicable percentage for the minimum gross sales for each subsequent calendar year. If iBio CDMO does not have sufficient total gross sales to offset this rent expense, it may adversely impact the Company's financial position and liquidity.

Risks Related to Business Operations

If we acquire companies, products or technologies, we may face integration risks and costs associated with those acquisitions that could negatively impact our business, results from operations and financial condition.

If we are presented with appropriate opportunities, we may acquire or make investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired business, and impairment charges if future acquisitions are not as successful as we originally anticipate. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets. Any failure to successfully integrate other companies, products or technologies that we may acquire may have a material adverse effect on our business and results of operations. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders.

We depend on key personnel and the loss of key personnel could harm our business and results of operations.

We depend on our ability to attract and retain qualified scientific and technical employees as well as a number of key executives. These employees may voluntarily terminate their employment with us at any time. There can be no assurance that we will be able to retain key personnel, or to attract and retain additional qualified employees. Our inability to attract and retain key personnel may have a material adverse effect on our business.

Risks Relating to Our Common Stock

iBio is subject to compliance under the NYSE American continued listing standards of the NYSE American Company Guide, the failure of which can result in delisting from the NYSE American.

In order to maintain its listing with NYSE American, we must remain in compliance with the continued listing standards as set forth in the NYSE American Company Guide (the "Company Guide"), including the listing standard set forth in Section 1003 of the Guide, which applies if a listed company has stockholders' equity below certain threshold amounts and has sustained losses from continuing operations and/or net losses in its five most recent fiscal years.

On October 16, 2019, we received notification from the NYSE American (the "Exchange") that we were not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide (the "Guide"), which applies if a listed company has stockholders' equity of less than $4,000,000 and has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years, and Section 1003(a)(iii) of the Guide, which applies if a listed company has stockholders' equity of less than $6,000,000 and has reported losses from continuing operations and/or net losses in its five most recent fiscal years. On December 9, 2019, we received a further notice from the Exchange that we were below the Exchange's continued listing standards set forth in Section 1003(a)(i) of the Guide, which applies if a listed company has stockholders' equity of less than $2,000,000 and has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years. The December 9, 2019 notification from the Exchange also stated that the Exchange had determined that our securities have been selling for a low price per share for a substantial period of time and pursuant to Section 1003(f)(v) of the Guide, our continued listing on the Exchange was predicated on us effecting a reverse stock split or otherwise demonstrating sustained improvement in its share price within a reasonable period of time, which the Exchange determined to be no later than June 9, 2020. The Exchange notified us on June 9, 2020, that we had regained compliance with this section of the Exchange's listing standards.

On January 10, 2020, we received notice from the Exchange that NYSE Regulation has accepted our November 15, 2019 plan to regain compliance with the Exchange's continued listing standards set forth in Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Guide and has granted a plan period through December 9, 2020, subject to periodic review by the Exchange, including quarterly monitoring, to regain compliance with the initiatives outlined in the plan. The Exchange notified us on October 1, 2020, that we had regained compliance with all of the Exchange's continued listing standards set forth in Part 10 of the Guide. Specifically, the notification stated that we had resolved the continued listing deficiency with respect to Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Guide by meeting the requirements of the $50 million market capitalization exemption in Section 1003(a) of the Guide.

There can be no assurance that we will continue to meet all of the Exchange's continued listing standards, or exemptions therefrom, in the future.

Our operating results may vary significantly in the future, which may adversely affect the price of our common stock.

It is likely that our operating results may vary significantly in the future and that period-to-period comparisons of our operating results are not necessarily meaningful indicators of the future. You should not rely on the results of one quarter as an indication of our future performance. It is also possible that in some future quarters our operating results will fall below our expectations or the expectations of market analysts and investors. If we do not meet these expectations, the price of our common stock may decline significantly.

Provisions in our certificate of incorporation, bylaws and under Delaware law could discourage a takeover that stockholders may consider favorable.

Provisions of our certificate of incorporation, bylaws and provisions of applicable Delaware law may discourage, delay or prevent a merger or other change in control that a stockholder may consider favorable. Pursuant to our certificate of incorporation, our Board of Directors may issue additional shares of common stock or preferred stock. Any additional issuance of common stock could have the effect of impeding or discouraging the acquisition of control of us by means of a merger, tender offer, proxy contest or otherwise, including a transaction in which our stockholders would receive a premium over the market price for their shares, and thereby protect the continuity of our management. Specifically, if in the due exercise of its fiduciary obligations, the Board of Directors were to determine that a takeover proposal was not in our best interest, shares could be issued by our Board of Directors without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover by:

- diluting the voting or other rights of the proposed acquirer or insurgent stockholder group,
- putting a substantial voting bloc in institutional or other hands that might undertake to support the incumbent Board of Directors, or
- effecting an acquisition that might complicate or preclude the takeover.

Our certificate of incorporation also allows our Board of Directors to fix the number of directors in the by-laws. Our certificate of incorporation does not contemplate cumulative voting in the election of directors and thus, under Delaware law, cumulative voting in the election of directors is not permitted. The effect of these provisions may be to delay or prevent a tender offer or takeover attempt that a stockholder may determine to be in his, her or its best interest, including attempts that might result in a premium over the market price for the shares held by the stockholders.

We have a staggered Board of Directors, which could impede an attempt to acquire the Company or remove our management.

Our Board of Directors is divided into three classes, each of which serves for a staggered term of three years. This division of our Board of Directors could have the effect of impeding an attempt to take over our company or change or remove management, since only one class will be elected annually. Thus, only approximately one-third of the existing Board of Directors could be replaced at any election of directors.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends.

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

The sale of our common stock through current or future equity offerings may cause dilution and could cause the price of our common stock to decline.

We are entitled under our certificate of incorporation, as amended, to issue up to 275,000,000 shares of our common stock and 1,000,000 shares of preferred stock.

On June 26, 2018, we closed an underwritten public offering with total gross proceeds of approximately $16,000,000, before deducting underwriting discounts, commissions and other offering expenses payable by us. The securities offered by us consisted of (i) 4,350,000 shares of common stock at $0.90 per share, (ii) 6,300 shares of Series A Convertible Preferred Stock, with a stated value of $1,000 per preferred share, and convertible into an aggregate of 7,000,000 shares of common stock at $0.90 per share, (iii) 5,785 shares of Series B Convertible Preferred Stock, with a stated value of $1,000 per preferred share, and convertible into an aggregate of 6,427,778 shares of common stock at $0.90 per share. We granted the underwriters Alliance Global Partners, a 45-day option to purchase up to an additional 2,666,666 shares of common stock to cover over-allotments, if any. On July 12, 2018, we received approximately $1,350,000, before deducting underwriting discounts, commissions and other offering expenses payable by us, from the proceeds of the sale of 1,500,000 over-allotment shares of common stock purchased at $0.90 by the underwriter during the 45-day provision.

On October 29, 2019, we closed a public offering of (i) 2,450,000 shares of our common stock, (ii) 4,510 shares of our Series C Convertible Preferred Stock, (iii) 25,000,000 Series A warrants to purchase shares of our common stock and (iv) 25,000,000 Series B warrants to purchase shares of our common stock. The net proceeds to us from the sale of these securities was approximately $4.5 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

As of the date of the filing of this Annual Report, we issued and sold an aggregate of (i) 28,394,064 shares of our common stock for gross proceeds of $66,879,647 pursuant to the equity distribution agreement with UBS Securities, (ii) 19,473,013 shares of our common stock for gross proceeds of $25,228,437 pursuant to the Lincoln Park March 2020 Purchase Agreement and 815,827 shares of our common stock as a commitment fee to Lincoln Park, and (iii) 1,000,000 shares of our common stock for gross proceeds of $1,090,000 in our offering in May 2020 with Lincoln Park.

As of October 8, 2020, we had issued and outstanding approximately 180.3 million shares of common stock and one share of iBio CMO Preferred Tracking Stock. As of October 9, 2020, 3.47 million options to purchase shares of common stock were outstanding and we had approximately2.9 million shares of common stock reserved for future issuance of additional option grants under our 2018 Omnibus Equity Incentive Plan, as amended.

Accordingly, we will be able to issue up to approximately33.4 million additional shares of common stock and 999,999 shares of preferred stock. Sales of our common stock offered through current or future equity offerings may result in substantial dilution to our stockholders. The sale of a substantial number of shares of our common stock to investors, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

The issuance of preferred stock or additional shares of common stock could adversely affect the rights of the holders of shares of our common stock.

Our Board of Directors is authorized to issue up to 999,999 shares of preferred stock without any further action on the part of our stockholders. Our Board of Directors has the authority to fix and determine the voting rights, rights of redemption and other rights and preferences of preferred stock. Currently, we have one share of preferred stock outstanding. Our Board of Directors may, at any time, designate a new series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock, and the right to the redemption of the shares, together with a premium, before the redemption of our common stock and authorize the issuance of such series of preferred stock, which may have a material adverse effect on the rights of the holders of our common stock. In addition, our Board of Directors, without further stockholder approval, may, at any time, issue large blocks of preferred stock. In addition, the ability of our Board of Directors to designate and issue shares of preferred stock without any further action on the part of our stockholders may impede a takeover of our company and may prevent a transaction that is favorable to our stockholders.

We rely extensively on our information technology systems and are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the sales and marketing of our products and services, we may from time to time transmit confidential information. We also expect to have access to, collect or maintain private or confidential information regarding any clinical trials conducted by us and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We have identified a material weakness in our internal controls over financial reporting, and we cannot provide assurances that this weakness has been effectively remediated or that additional material weaknesses will not occur in the future.

As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes-Oxley Act. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal control over financial reporting.

Our management has identified a material weakness in our internal control over financial reporting and has concluded that, due to such material weakness, which related to certain sales of common stock being recorded on the settlement date as opposed to the trade date, our disclosure controls and procedures and our internal control over financial reporting were not effective as of June 30, 2020 and March 31, 2020. If not remediated properly, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our common stock. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we may eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Property.

As discussed above, iBio CDMO's operations take place in Bryan, Texas, in a facility controlled by the Second Eastern Affiliate as sublandlord. The facility is a 130,000-square foot Class A life sciences building located on land owned by the Texas A&M system, designed and equipped for plant-made development and manufacture of biopharmaceuticals. iBio CDMO has a 34-year sublease for the facility that terminates in 2050 which may be extended by iBio CDMO for a ten-year period, so long as iBio CDMO is not in default under the lease.

In addition to the base rent of $2,100,000 iBio CDMO is required to pay to the Second Eastern Affiliate, for each calendar year during the term, a portion of the total gross sales for products manufactured or processed at the facility, equal to 7% of the first $5,000,000 of gross sales, 6% of gross sales between $5,000,001 and $25,000,000, 5% of gross sales between $25,000,001 and $50,000,000, 4% of gross sales between $50,000,001 and $100,000,000, and 3% of gross sales between $100,000,001 and $500,000,000. However, if for any calendar year period from January 1, 2018 through December 31, 2019, iBio CDMO's applicable gross sales are less than $5,000,000, or for any calendar year period from and after January 1, 2020, its applicable gross sales are less than $10,000,000, then iBio CDMO is required to pay the amount that would have been payable if it had achieved such minimum gross sales and shall pay no less than the applicable percentage for the minimum gross sales for each subsequent calendar year. If iBio CDMO does not have sufficient total gross sales to offset this rent expense, it may adversely impact the Company's financial position and liquidity.

Item 3. Legal Proceedings.

Lawsuits

On March 17, 2015, the Company filed a Verified Complaint in the Court of Chancery of the State of Delaware against Fraunhofer and Vidadi Yusibov ("Yusibov"), Fraunhofer Center for Molecular Biology's Executive Director, seeking monetary damages and equitable relief based on Fraunhofer's material and continuing breaches of its contracts with the Company. On September 16, 2015, the Company voluntarily dismissed its action against Yusibov, without prejudice, and thereafter on September 29, 2015, the Company filed a Verified Amended Complaint against Fraunhofer alleging material breaches of its agreements with the Company and seeking monetary damages and equitable relief against Fraunhofer. The Court bifurcated the action to first resolve the threshold question in the case–the scope of iBio's ownership of the technology developed or held by Fraunhofer–before proceeding with the rest of the case and the parties stipulated their agreement to that approach. After considering the parties' written submissions and oral argument, the Court resolved the threshold issue in favor of iBio on July 29, 2016, holding that iBio owns all proprietary rights of any kind to all plant-based technology of Fraunhofer developed or held as of December 31, 2014, including know-how, and was entitled to receive a technology transfer from Fraunhofer. Fraunhofer's motion to dismiss iBio's contract claims was denied by the Court on February 24, 2017. The Court at that time also granted, over Fraunhofer's opposition, iBio's motion to supplement and amend the Complaint to add additional state law claims against Fraunhofer. Fraunhofer filed an answer and counterclaims in March 2017, but in May 2017, Fraunhofer obtained new counsel, and with iBio's agreement (as a matter of procedure), filed an amended answer and amended counterclaims in July 2017. The Company replied to those counterclaims on August 9, 2017. In November 2017, the Company engaged new counsel to further lead its litigation efforts, and on November 3, 2017, the Company filed a separate Verified Complaint in the Court of Chancery of the State of Delaware against Fraunhofer-Gesellschaft, the European unit of Fraunhofer (the "Second Complaint"). The Second Complaint follows iBio's pending litigation filed in March 2015, described above, against Fraunhofer USA, Inc., the U.S. unit of Fraunhofer. On December 10, 2018, the Delaware Chancery Court dismissed the Second Complaint filed against Fraunhofer-Gesellschaft, the European unit of Fraunhofer, as untimely filed. The dismissal of the Second Complaint has no effect on the action against the U.S. unit of Fraunhofer.

The case against Fraunhofer has proceeded and fact and expert discovery has now closed.

Fraunhofer filed a motion for summary judgment in November 2019 arguing that the Company's claims should be dismissed as preempted or duplicative, and that certain claims should be time barred. Briefing was completed in January 2020, and a hearing on Fraunhofer's motion was held on June 11, 2020. On September 25, 2020, the Court granted in part and denied in part Fraunhofer's motion for summary judgment. The Court granted Fraunhofer's motion for summary judgment as to iBio's fraud, conversion, constructive trust, partial rescission, and unjust enrichment claims. The Court denied Fraunhofer's motion for summary judgment as to iBio's declaratory judgment, breach of contract, misappropriation of trade secrets, tortious interference, and deceptive trade practices claims, and ruled that those claims could proceed to trial.

On January 6, 2020, the Company filed a motion in the Court of Chancery of the State of Delaware to initiate new litigation against Fraunhofer-Gesellschaft through an amendment to its Verified Amended Complaint. The motion asserts that new evidence reveals that Fraunhofer-Gesellschaft exercised complete dominion and control over its US subsidiary to wrongfully access and direct use of iBio's intellectual property on many occasions with new and different third parties. The Court denied the Company's motion for leave to amend at a hearing on June 11, 2020, without prejudice and with leave to refile the complaint at a later date.

The case is set for trial on March 1 to 5, 2021. The Company is unable to predict the further outcome of this action at this time.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the NYSE American under the trading symbol "IBIO."

Holders

As of October 5, 2020, there were 93 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our common stock. Dividends on our common stock cannot be declared or paid or set aside for payment or other distribution unless all accrued dividends on all outstanding shares of Preferred Tracking Stock are paid in full.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities other than as set forth in documents previously filed by the Company with the SEC.

Item 6. Selected Financial Data.

The information under this Item is not required to be provided by smaller reporting companies.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read together with our financial statements and the notes thereto and other information included elsewhere in this Annual Report on Form 10-K.

Overview

We are a biotechnology company and biologics contract development and manufacturing organization ("CDMO"). We apply our licensed and owned technologies to develop novel products to fight fibrotic diseases, cancers, and infectious diseases. We use our *FastPharming*® Development and Manufacturing System to increase "speed-to-clinic" for new candidates. We are also using the *FastPharming* System to create proteins and bioinks for research and further manufacturing uses in a variety of R&D applications, including 3D-bioprinting. In addition, we make the *FastPharming* System available to clients on a fee-for-service basis for the rapid, scalable, eco-friendly production of high-quality proteins.

During the year ended June 30, 2020, we operated in two segments: (i) our CDMO segment, operated via our subsidiary iBio CDMO, and (ii) our biologics development and licensing activities, conducted within iBio, Inc. In the past, our primary focus was the CDMO business, pursuant to which iBio CDMO provided manufacturing services to collaborators and third-party customers as well as used for development of our own product candidates. However, during the second half of 2020 and subsequent to year end, we shifted our primary focus to our biologics development programs, including new vaccines and therapeutics.

Our current platforms and programs include: (i) CDMO services using our licensed and owned *FastPharming* Technologies and *Glycaneering*™ Services; (ii) the development of therapeutics, for which we intend to conduct preclinical and clinical trials; (iii) the development of vaccines, for which we intend to conduct preclinical and clinical trials, and (iv) the production of proteins for research and further manufacturing use in 3D-bioprinting and other applications. We are developing a portfolio of technologies, products, and services driven by the following platforms and programs, which we intend to use individually, and in combination:

- **CDMO Services**
  - Process development and manufacturing of protein products in hydroponically-grown, transiently-transfected plants, (typically *Nicotiana benthamiana,* a relative of the tobacco plant) via utilization of our proprietary expression technologies, *Glycaneering* Services, and production know-how (the *FastPharming* System) deployed in our 130,000 square-foot manufacturing facility in Bryan, Texas.
  - "Factory Solutions" for the clients who seek to insource biologics manufacturing using the *FastPharming* System and instead of outsourcing production to iBio CDMO.

- **Therapeutics**
  - Treatments for fibrotic diseases, including a fusion of the endostatin-derived E4 antifibrotic peptide to the hinge and heavy chain of human IgG1 ("IBIO-100", formerly described as "CFB-03") for systemic scleroderma (for which we have received orphan drug designation), idiopathic pulmonary fibrosis, and related conditions.
  - An ACE2-Fc fusion protein as a treatment for COVID-19 and, prospectively, other diseases emanating from the Coronaviridae family, in-licensed from Planet Biotechnology, Inc.

- **Vaccines**
  - A novel virus-like particle antigen being designed for use in a vaccine candidate targeting the SARS-CoV-2 virus ("IBIO-200").
  - The lichenase ("*LicKM™*")-subunit vaccine for COVID-19 ("IBIO-201").
  - An E2 antigen, in combination with a selected adjuvant, for vaccination of pigs against classical swine fever ("IBIO-400").

- **Research & Bioprocess Products**
  - Protein scaffolds for use as bioinks in the development of 3D-bioprinted tissues and organs.
  - Cytokines and growth factors for cell culture applications.
  - Biomaterials for a range of life science research, development, and bioprocessing applications.

Results of Operations

Revenue

Gross revenue for 2020 and 2019 was approximately $1,638,000 and $2,018,000, respectively, a decrease of $380,000 (19%). The decrease is primarily attributable to the timing of revenue earned under the strategic relationship with CC-Pharming. Revenue earned from CC-Pharming totaled approximately $1,268,000 in 2020 as compared to $1,848,000 in 2019, a decrease of $580,000 (31%). In addition, in 2020, the Company entered into a Master Manufacturing Services and Supply Agreement ("MSA") with Lung Bio to produce recombinant human collagen-based bioinks for 3D-bioprinted organ transplants. Revenue earned from the MSA totaled $46,000. Revenue earned from other third-party customers in 2020 totaled approximately $325,000 versus $170,000 in 2019, an increase of $155,000 (91%).

Research and Development Expenses

Research and development expenses for 2020 and 2019 were approximately $3,213,000 and $5,474,000, respectively, a decrease of $2,261,000. The decrease primarily related to decreases in third-party research and development costs of approximately $1,404,000, research and development personnel and consulting costs of approximately $963,000 and grant income of $37,000, offset by an increase in research and development project related costs of $112,000.

General and Administrative Expenses

General and administrative expenses for 2020 and 2019 were approximately $12,428,000 and $12,332,000, respectively, an increase of $96,000. General and administrative expenses principally include officer and employee salaries and benefits, depreciation and amortization, professional fees, facility repairs and maintenance, rent, utilities, consulting services, and other costs associated with being a publicly traded company. The increase is primarily attributable to increases in depreciation and amortization expense of $492,000, professional fees of $508,000, personnel costs of $380,000 and Board of Directors' fees of $168,000; offset by decreases in repairs and maintenance costs of approximately $817,000, rent of $409,000, recruiting fees of $131,000, and travel of $212,000.

Other Income (Expense)

Other income (expense) for 2020 and 2019 was approximately $(2,441,000) and $(1,809,000), respectively.

The increase resulted primarily from an increase in interest expense related to the adoption, effective July 1, 2019, of ASU 2016-02, "*Leases (Topic 842)*" ("ASU 2016-02") ("ASC 842") and other associated standards using the modified retrospective approach for all leases entered into before the effective date. The adoption of ASC 842 had a significant effect on our balance sheet resulting in an increase in non-current assets and both current and non-current liabilities and an associated $566,000 interest expense.

As discussed above, iBio CDMO's operations take place in a facility in Bryan, Texas under Sublease with the Second Eastern Affiliate. Such sublease is treated as a finance lease. In 2020, other income (expense) included interest expense of $2,466,000 incurred under the finance lease offset by interest and royalty income of $25,000. Other income (expense) in 2019 included interest expense of $1,900,000 incurred under the capital lease offset by interest and royalty income of $91,000.

Net Loss Attributable to Noncontrolling Interest

This represents the share of the loss in iBio CDMO for the Eastern Affiliate in 2020 and 2019.

Liquidity and Capital Resources

As of June 30, 2020, we had cash of $55.1 million as compared to $4.4 million as of June 30, 2019. Given that our total cash and marketable securities as of October 8, 2020, exceeded $83 million, we believe that our current cash will be sufficient to support our current operations through fiscal year 2022.

The following equity transactions occurred during Fiscal 2020:

1. On October 29, 2019, the Company closed on an underwritten public offering with total net proceeds of $4.5 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company.

2. On March 19, 2020, the Company entered into the Lincoln Park March 2020 Purchase Agreement pursuant to which Lincoln Park agreed to purchase from the Company up to an aggregate of $50,000,000 of the Company's common stock (subject to certain limitations) from time to time over the 36-month term. As of June 30, 2020, Lincoln Park has acquired 16.8 million shares of the Company's common stock for gross proceeds of approximately $18.4 million. From July 1, 2020 through July 27, 2020, Lincoln Park has acquired 2.7 million shares of the Company's common stock for gross proceeds of approximately $6.8 million. No further sales of shares of our common stock will be made since we terminated the Lincoln Park March 2020 Purchase Agreement effective July 27, 2020.

3. On May 13, 2020, the Company entered into a purchase agreement, pursuant to which the Company sold to Lincoln Park 1,000,000 shares of the Company's common stock at a price of $1.09 per share for an aggregate purchase price of $1.1 million.

4. On June 17, 2020 as amended on July 29, 2020, the Company entered into an equity distribution agreement with UBS Securities as sales agent pursuant to which the Company may sell from time to time shares of its common stock through UBS Securities, for the sale of up to $72,000,000 of shares of the Company's common stock. As of June 30, 2020, approximately 19.8 million shares of the Company's common stock were issued for net proceeds of approximately $42.2 million. From July 1, 2020 through the date of the filing of this Annual Report, approximately 8.6 million shares of Common Stock were issued for net proceeds totaling approximately $24.6 million.

5. In Fiscal 2020, the Company received proceeds of $6.3 million from the exercise of various warrants.

Net Cash Used in Operating Activities

Operating activities used $13.3 million in cash in 2020. The decrease in cash was attributable to funding our net loss for the year offset by an increase in accounts payable, accrued expenses and contract liabilities related to contract liability amounts.

Net Cash Used in Investing Activities

Net cash used in investing activities was approximately $1,154,000 for 2020. Cash used in investing activities was attributable to the additions of intangible assets of $76,000 and fixed assets attributable to iBio CDMO of $1,078,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $65,192,000 in Fiscal 2020, which represented (1) the net proceeds from the October 2019 public offering; (2) the net proceeds from the Lincoln Park March 2020 Purchase Agreement; (3) the proceeds from the agreement with Lincoln Park; (4) the net proceeds from the equity distribution agreement with UBS Securities; (5) the proceeds from the exercises of Warrants; and (6) the proceeds from the PPP loan net of the repayment of notes issued under the Warrant Exchange and the payments under the finance lease obligation.

Funding Requirements

We have incurred significant losses and negative cash flows from operations since our spin-off from Integrated BioPharma in August 2008. As of June 30, 2020, our accumulated deficit was approximately $150.4 million, and we used approximately $13.3 million of cash for operating activities for Fiscal 2020.

In the past, the history of significant losses, the negative cash flow from operations, the limited cash resources on hand and the dependence by the Company on its ability – about which there was no certainty – to obtain additional financing to fund its operations after the current cash resources are exhausted raised substantial doubt about the Company's ability to continue as a going concern. Based on the total cash on hand of approximately $55.1 million as of June 30, 2020, combined with subsequent purchases of the Company's common stock by Lincoln Park totaling approximately $6.8 million and sales of common stock through the equity distribution agreement with UBS Securities through the date of the filing of this Annual Report totaling approximately $66.9 million, we believe the Company has adequate cash on hand to support the Company's activities through fiscal year 2022.

We plan to fund our future business operations using cash on hand, through proceeds realized in connection with the commercialization of our technologies and proprietary products, license and collaboration arrangements and the operation of iBio CDMO, and through proceeds from the sale of additional equity or other securities. We cannot be certain that such funding will be available on favorable terms or available at all. To the extent that the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. If we are unable to raise funds when required or on favorable terms, this assumption may no longer be operative, and we may have to: a) significantly delay, scale back, or discontinue the product application and/or commercialization of our proprietary technologies; b) seek collaborators for our technology and product candidates on terms that are less favorable than might otherwise be available; c) relinquish or otherwise dispose of rights to technologies, product candidates, or products that we would otherwise seek to develop or commercialize; or d) possibly cease operations.

Off-Balance Sheet Arrangements

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities (SPEs), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually limited purposes. As of June 30, 2020, we were not involved in any SPE transactions.

Critical Accounting Policies and Estimates

A critical accounting policy is one that is both important to the portrayal of a company's financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All applicable U.S. GAAP accounting standards effective as of June 30, 2020 have been taken into consideration in preparing the consolidated financial statements. The preparation of consolidated financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Some of those estimates are subjective and complex, and, consequently, actual results could differ from those estimates. The following accounting policies and estimates have been highlighted as significant because changes to certain judgments and assumptions inherent in these policies could affect our consolidated financial statements:

- valuation of intellectual property;
- revenue recognition;
- legal and contractual contingencies;
- research and development expenses; and
- share-based compensation expenses.

We base our estimates, to the extent possible, on historical experience. Historical information is modified as appropriate based on current business factors and various assumptions that we believe are necessary to form a basis for making judgments about the carrying value of assets and liabilities. We evaluate our estimates on an ongoing basis and make changes when necessary. Actual results could differ from our estimates. See Note 3 to the consolidated financial statements in this Annual Report for a complete discussion of our significant accounting policies and estimates.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The information under this Item is not required to be provided by smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

Financial statements and notes thereto appear on pages F-1 to F-32 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

Our management, under the direction of our Chief Executive Officer and Principal Financial Officer and Principal Accounting Officer have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of June 30, 2020. Based on that evaluation, our Chief Executive Officer and Principal Financial Officer and Principal Accounting Officer have concluded that our disclosure controls and procedures were not effective as of June 30, 2020 due to a control failure related to the sales of common stock that were recorded on the settlement date rather than the trade date basis which resulted from ineffective review for compliance with US GAAP and that was not detected on a timely basis. Management evaluated this internal control deficiency and concluded that the control over the recording of sales of common stock did not operate effectively and is a material weakness.

As of the end of the period covered by this Annual Report, we evaluated, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer and Principal Accounting Officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Management necessarily applied its judgment in assessing the costs and benefits of those controls and procedures, which by their nature, can provide only reasonable assurance about management's control objectives. You should note that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. Based upon this evaluation, our Chief Executive Officer and the Principal Financial Officer and Principal Accounting Officer concluded that as of June 30, 2020 our disclosure controls and procedures were not effective because of the material weakness in internal control over financial reporting described below. In light of the material weakness, management performed additional procedures to validate the accuracy and completeness of the financial results impacted by the control deficiency. Such procedures included the review of share purchase agreements, share purchase confirmations, transfer agent reports, and detailed testing.

Notwithstanding this material weakness, concluded that the financial statements included in this Annual Report present fairly, in all material respects, the financial position of iBio as of June 30, 2020 and 2019, and the results of its operations and its cash flows and changes in stockholders' equity for the years ended June 30, 2020 and 2019, in conformity with accounting principles generally accepted in the United States of America.

Management's Report on Internal Control over Financial Reporting

It is the responsibility of the management of iBio to establish and maintain effective internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Internal control over financial reporting is designed to provide reasonable assurance to iBio's management and board of directors regarding the preparation of reliable financial statements for external purposes in accordance with generally accepted accounting principles.

iBio's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of iBio; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of iBio are being made only in accordance with authorizations of management and directors of iBio; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of iBio's assets that could have a material effect on the financial statements of iBio.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Management has performed an assessment of the effectiveness of iBio's internal control over financial reporting as of June 30, 2020 based upon criteria set forth in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 COSO Framework).

Based on this assessment, management has concluded that our internal control over financial reporting was not effective as of June 30, 2020 as oucontrols over the recording common stock sales did not operate effectively. We failed to properly apply generally accepted accounting principles (GAAP) and record common stock sales timely during the quarters ended March and June 2020. This matter was identified by our independent registered public accounting firm, CohnReznick LLP and corrected by management during the quarter ended June 30, 2020. Management subsequently investigated all other stock trade transactions from fiscal year 2020. Management found the same material weakness concerning stock transactions in the quarter ended March 2020.

Material Weakness in Internal Control Over Financial Reporting

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. In the fiscal year 2020 fourth quarter, we identified the following deficiencies in the design of internal control over financial reporting related to our accounting for equity transactions.

There were not sufficient resources with an understanding of both the requirements under generally accepted accounting principles to properly record the issuance of common stock and the terms and conditions of the share purchase agreement governing these sale transactions to allow the individuals responsible for the accounting review and proper recording of the transactions to prevent or detect material misstatements on a timely basis in the normal course of their review.

These control deficiencies resulted in errors impacting total consolidated assets, equity and weighted average shares outstanding in our previously filed 10-Q for the three and nine month periods ended March 31, 2020. We concluded that the combination of control deficiencies represented a material weakness.

Plan for Remediation of Material Weakness

Management has developed and implemented a remediation plan to address the material weakness described above. The Company has modified existing internal controls and implemented additional internal controls related to the timely and accurate recording of non-routine transactions.

Changes in Internal Control Over Financial Reporting

Under the supervision and with the participation of our Chief Executive Officer and Principal Financial Officer and Principal Accounting Officer, our management has evaluated changes in our internal control over financial reporting that occurred during the third and fourth quarter of 2020. Based on that evaluation, except for the changes described above, our Chief Executive Officer and Principal Financial Officer and Principal Accounting Officer did not identify any change in our internal control over financial reporting during these periods that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report by CohnReznick LLP ("CohnReznick"), our independent registered public accounting firm, regarding internal control over financial reporting. As a smaller reporting company, our internal control over financial reporting was not subject to audit by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report.

Item 9B. Other Information.

On October 13, 2020 John Delta, our Principal Accounting Officer, was appointed as our Principal Financial Officer.

Mr. Delta, age 58, has served as our Principal Accounting Officer since October 1, 2020 and a consultant to the Company since July 13, 2020. Mr. Delta also serves (from November 2016 to the present) as Managing Partner, Mid-Atlantic of TechCXO LLC, a professional services firm that provides experienced, C-Suite professionals to deliver strategic and functional consulting services. From February 2011 to June 2016, he served as Chief Operating Officer of Management CV Inc., where he was responsible for all operational aspects of the business, including HR, Product Management, E-Commerce, Global Research and day to day Operations. From February 2010 to February 2011, Mr. Delta served as Co-Founder/Chief Financial Officer of JJAB Holdings, LLC, where he was responsible for Finance and Operations for this private-equity-backed startup in the direct response marketing space. He also served as Chief Financial Officer of Edison Worldwide, LLC from December 2008 to January 2010, where he led all accounting and strategic finance initiatives for this high growth Direct Response Marketing firm. From March 2006 to October 2008, Mr. Delta served as Chief Financial Officer of DoublePositive Marketing Group, Inc., where he built the accounting and finance functions for this high growth VC-backed firm. From October 2003 to December 2005, he served as Executive Vice President and Chief Operating Officer of Hemscott Group, PLC, a private-equity-backed roll-up in the financial information space. Mr. Delta led post-merger integration and operations for this global firm (US, UK and India) and he was instrumental in developing the successful exit strategy of splitting the firm in two and selling the retail component to Morningstar and the institutional piece to KKR. Mr. Delta also served as Vice President, General Manager of The Nasdaq Stock Market for almost 10 years, where he developed the business plan for, and then ran, the e-commerce group. Prior to working at Nasdaq, Mr. Delta worked as an Associate at McKinsey & Co. where he primarily worked with the Financial Institutions Group on strategic technology engagements and as a Manager at Deloitte & Touche where he focused on Financial Services. Mr. Delta holds a B.A. and a Master of Business Administration (MBA) from the University of Virginia.

Since July 2020, Mr. Delta has been providing financial consulting services to the Company under a Consulting and Services Agreement by and between the Company and TechCXO LLC, dated July 8, 2020 (the "Consulting Agreement"). Pursuant to the Consulting Agreement, the Company will pay Mr. Delta for his services as the Company's principal accounting officer at an hourly rate expected to represent approximately $30,000 per month, and to reimburse any reasonable out-of-pocket business expenses incurred by Mr. Delta in performing the services.

PART III

Certain information required by Part III is omitted from this Annual Report because we intend to file our definitive proxy statement for our 2020 Annual Meeting of Stockholders, pursuant to regulation 14A of The Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report and certain information to be included in the definitive proxy statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item that will appear under the headings "Governance," "Executive Officers," and "Delinquent Section 16(a) Reports" in the definitive proxy statement to be filed with the SEC relating to our 2020 Annual Meeting of Stockholders is incorporated herein by reference.

Code of Ethics

We have adopted a written code of ethics within the meaning of Item 406 of SEC Regulation S-K, which applies to all of our employees, including our principal executive officer and our chief financial officer, a copy of which can be found on our website at www.ibioinc.com. If we make any waivers or substantive amendments to the code of ethics that are applicable to our principal executive officer or our chief financial officer, we will disclose the nature of such waiver or amendment in a Current Report on Form 8-K in a timely manner. No waivers from any provision of our policy have been granted.

Item 11. Executive Compensation and Director Compensation

Information required by this Item that will appear under the heading "Executive Compensation" and "Director Compensation" in the definitive proxy statement to be filed with the SEC relating to our 2020 Annual Meeting of Stockholders is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this Item that will appear under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the definitive proxy statement to be filed with the SEC relating to our 2020 Annual Meeting of Stockholders is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this Item that will appear under the headings "Certain Relationships and Related Transactions" and "Independence of Board" in the definitive proxy statement to be filed with the SEC relating to our 2020 Annual Meeting of Stockholders is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this Item that will appear under the heading "Independent Auditor Fees and Other Matters" in the definitive proxy statement to be filed with the SEC relating to our 2020 Annual Meeting of Stockholders is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Exhibits and Index

(1) A list of the financial statements filed as part of this Annual Report is set forth in the index to financial statements at page F-1 and is incorporated herein by reference.

(2) An exhibit index is incorporated by reference or filed with this Annual Report is provided below:

Item 16. Form 10-K Summary

Not Applicable

EXHIBIT INDEX

Exhibit No.	Description
1.1	Equity Distribution Agreement dated June 17, 2020, by and between iBio, Inc. and UBS Securities LLC (Incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K, filed with by iBio, Inc. with the Securities and Exchange Commission on June 17, 2020)
1.2	Amendment No. 1 to Equity Distribution Agreement, dated June 29, 2020, by and between iBio, Inc. and UBS Securities LLC (Incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 29, 2020)
1.3	Underwriting Agreement between iBio, Inc. and A.G.P/ Alliance Global Partners (Incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 29, 2019 - File No. 001-35023)
3.1	Certificate of Incorporation of iBio, Inc., Certificate of Merger, Certificate of Ownership and Merger, Certificate of Amendment of the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 11, 2018 - File No. 001-35023))
3.2	Certificate of Amendment of the Certificate of Incorporation of iBio, Inc. (incorporated herein by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 14, 2018 - File No. 001-35023)
3.3	Certificate of Amendment of the Certificate of Incorporation of iBio, Inc. (incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on June 8, 2018 - File No. 001-35023)
3.4	First Amended and Restated Bylaws of iBio, Inc. (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2009 - File No. 000-53125)
3.5	Certificate of Designation, Preferences and Rights of the iBio CMO Preferred Tracking Stock of iBio, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 24, 2017 - File No. 001-35023)
3.6	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of iBio, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2018 - File No. 001-35023)
3.7	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock of iBio, Inc. (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2018 - File No. 001-35023)
3.8	Certificate of Designation, Preferences and Rights of the Series C Convertible Preferred Stock of iBio, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2019 - File No. 001-35023)

4.1	Form of Common Stock Certificate (Incorporated herein by reference to Exhibit 4.1 to the Company's Form 10-12G filed with the Securities and Exchange Commission on July 11, 2008 - Commission File No. 000-53125)
4.2	Registration Rights Agreement, dated July 24, 2017, between the Company and Lincoln Park Capital Fund, LLC (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on July 24, 2017 - Commission File No. 001-35023)
4.3	Registration Rights Agreement, dated March 19, 2020, between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 20, 2020 - File No. 001-35023)
4.4	Form of Series A Warrant to Purchase Common Stock (incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on October 28, 2019 - Commission File No. 001-35023)
4.5	Form of Amended and Restated Series A Warrant to Purchase Common Stock (incorporated herein by reference to Exhibit 4.1 the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2020 - File No. 001-35023)
4.5	Form of Series B Warrant to Purchase Common Stock (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on October 28, 2019 - Commission File No. 001-35023)
4.6	Form of Amended and Restated Series B Warrant to Purchase Common Stock (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on February 21, 2020 - File No. 001-35023)
4.7	Form of Promissory Note, by and between certain holders of the Company's Series A Warrants, in the aggregate principal amount of $3.3 Million (incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on February 25, 2020 – File No. 001-35023)
4.8	Warrant Exchange and Amendment Agreement, by and between iBio, Inc. and certain security holders, dated February 20, 2020 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2020 – File No. 001-35023)
4.9*	Description of Securities of iBio, Inc.
10.1	Technology Transfer Agreement, dated as of January 1, 2004, between the Company and Fraunhofer USA Center for Molecular Biotechnology, Inc. as amended (incorporated herein by reference to Exhibit 10.6 to the Company's Form 10-12G filed with the SEC on June 18, 2008 - Commission File No. 000-53125)
10.2+	Ratification dated September 6, 2013 of Terms of Settlement by and between the Company and Fraunhofer USA Center for Molecular Biotechnology, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2013, filed with the SEC on September 30, 2013 - Commission File No. 001-35023).
10.3	Share Purchase Agreement, dated January 13, 2016, between iBio, Inc. and Eastern Capital Limited, for the purchase of 3,500,000 (pre-split) shares of common stock Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on January 14, 2016 - File No. 000-35023).
10.4	Share Purchase Agreement, dated January 13, 2016, between iBio, Inc. and Eastern Capital Limited, for the purchase of 6,500,000 (pre-split) shares of common stock (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on January 14, 2016 - File No. 000-35023)
10.5	Amendment, dated June 26, 2018, to Share Purchase Agreement, dated January 13, 2016, between iBio, Inc. and Eastern Capital Limited, for the purchase of 6,500,000 (pre-split) shares of common stock (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on June 27, 2018 - File No. 001-35023)
10.6	Amended and Restated Limited Liability Company Operating Agreement of iBio CDMO LLC, dated January 13, 2016, between the Company, Bryan Capital Investors LLC and iBio CDMO LLC (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 22, 2016 - File No. 001-35023)

10.7	License Agreement, dated January 13, 2016, between the Company and iBio CDMO LLC (Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on February 22, 2016 - File No. 001-35023)
10.8	Sublease Agreement, dated January 13, 2016, between College Station Investors LLC and iBio CDMO LLC (Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 22, 2016 - File No. 001-35023)
10.9	Exchange Agreement, dated February 23, 2017, between iBio, Inc. and Bryan Capital Investors LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 24, 2017 - File No. 001-35023)
10.10	Amendment No. 1 to the Amended and Restated Limited Liability Company Agreement of iBio CDMO LLC, dated February 23, 2017, (incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on February 24, 2017- File No. 001-35023)
10.11**	Offer Letter, dated December 30, 2016, between iBio, Inc. and James P. Mullaney (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 6, 2017 (File No. 001-35023)
10.12	Purchase Agreement, dated July 24, 2017, between iBio, Inc. and Lincoln Park Capital Fund, LLC (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on July 24, 2017 - Commission File No. 001-35023)
10.13**	Form of Directors and Officer Indemnification Agreement (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2019 (Commission File No. 001-35023)
10.14**	Executive Employment Agreement, dated as of March 10, 2020, between iBio, Inc. and Thomas F. Isett (Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on March 13, 2020 (Commission File No. 001-35023)
10.15	Purchase Agreement dated as of March 19, 2020 by and between iBio, Inc and Lincoln Park Capital Fund, LLC (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 20, 2020 (Commission File No. 001-35023)
10.16**	Amended and Restated Executive Employment Agreement, dated as of April 21, 2020, between iBio, Inc. and Thomas F. Isett (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 24, 2020 (Commission File No. 001-35023)
10.17	Purchase Agreement, dated as of May 13, 2020, between iBio, Inc. and Lincoln Park Capital Fund, LLC (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 20, 2020 – Commission File No. 001-35023)
10.18**	Transition Agreement, dated June 12, 2020, between Robert Kay and iBio, Inc. (incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on June 17, 2020 – File No. 001-35023)
10.19**	2018 Omnibus Equity Incentive Plan, effective December 18, 2018 (incorporated herein by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K filed with the SEC on August 26, 2019 - File No. 001-35023)
10.20**	Amended and Restated 2018 Omnibus Equity Incentive Plan, effective December 18, 2018 (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement filed with the SEC on January 23, 2020 - File No. 001-35023)
10.21**	Transition Agreement, dated June 12, 2020, between Robert Kay and iBio, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on June 17, 2020 - File No. 001-35023)
10.22**	Form of Stock Option Agreement by and between iBio, Inc. and Robert Kay (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on June 17, 2020 - File No. 001-35023)
21.1*	Subsidiaries of Registrant
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Periodic Report by Chief Executive Officer Pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Periodic Report by Principal Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Periodic Report by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2*	Certification of Periodic Report by Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS	XBRL Instance*
101.SCH	XBRL Taxonomy Extension Schema*
101.CAL	XBRL Taxonomy Extension Calculation*
101.DEF	XBRL Taxonomy Extension Definition*
101.LAB	XBRL Taxonomy Extension Labeled*
101.PRE	XBRL Taxonomy Extension Presentation*

* Filed herewith.
** Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this Annual Report.
+ Confidential treatment requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

iBio, Inc.
(Registrant)

Dated: October 13, 2020

/s/ Thomas F. Isett 3rd
Thomas F. Isett 3rd
Chairman and Chief Executive Officer

/s/ John Delta
Principal Accounting Officer
(Principal Financial Officer and Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Title	Date
/s/Thomas F. Isett 3rd Thomas F. Isett 3rd	Chairman, Chief Executive Officer (Principal Executive Officer)	October 13, 2020
/s/John Delta John Delta	Principal Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	October 13, 2020
/s/Robert B. Kay Robert B. Kay	Director	October 13, 2020
/s/Glenn Chang Glenn Chang	Director	October 13, 2020
/s/Seymour Flug Seymour Flug	Director	October 13, 2020
/s/James T. Hill General James T. Hill, USA (Retired)	Director	October 13, 2020
/s/John D. McKey, Jr. John D. McKey, Jr.	Director	October 13, 2020
/s/Philip K. Russell Philip K. Russell, M.D.	Director	October 13, 2020

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iBio, Inc.

Financial Statement Index

Report of Independent Registered Public Accounting Firm

The Board of Directors and
Stockholders of iBio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of iBio, Inc. and Subsidiaries (the "Company") as of June 30, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2020 and 2019, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2010.

Holmdel, New Jersey

October 13, 2020

iBio, Inc. and Subsidiaries
Consolidated Balance Sheets
(In Thousands, except share and per share amounts)

	June 30, 2020	June 30, 2019
Assets		
Current assets:		
Cash	**$ 55,112**	$ 4,421
Accounts receivable - trade	**75**	97
Subscription receivable	**5,549**	-
Work in progress	**798**	-
Prepaid expenses and other current assets	**214**	290
Total Current Assets	**61,748**	4,808
Finance lease right-of-use assets, net of accumulated amortization	**27,616**	-
Fixed assets, net of accumulated depreciation	**3,657**	24,380
Intangible assets, net of accumulated amortization	**1,144**	1,374
Security deposit	**24**	24
Total Assets	**$ 94,189**	$ 30,586
Liabilities and Equity		
Current liabilities:		
Accounts payable (related party of $6 and $125 as of June 30, 2020 and 2019, respectively)	**$ 1,759**	$ 1,001
Accrued expenses (related party of $705 and $699 as of June 30, 2020 and 2019, respectively)	**1,105**	965
Note payable – PPP Loan – current portion	**261**	-
Finance lease obligation – current portion	**301**	-
Capital lease obligation - current portion	**-**	213
Contract liabilities	**1,810**	1,279
Total Current Liabilities	**5,236**	3,458
Note payable – PPP Loan – net of current portion	**339**	-
Finance lease obligation – net of current portion	**32,007**	-
Capital lease obligation - net of current portion	**-**	24,671
Total Liabilities	**37,582**	28,129
Commitments and Contingencies		
Equity		
iBio, Inc. Stockholders' Equity:		
Preferred stock - no par value; 1,000,000 shares authorized;		
iBio CMO Preferred Tracking Stock; 1 share authorized, issued and outstanding as of both June 30, 2020 and 2019	**-**	-
Series A Convertible Preferred Stock - $1,000 stated value; 6,300 shares authorized; 0 and 3,987 shares issued and outstanding as of June 30, 2020 and 2019, respectively	**-**	-
Series B Convertible Preferred Stock - $1,000 stated value; 5,785 shares authorized; 5,785 shares issued and outstanding as of both June 30, 2020 and 2019	**-**	-
Series C Convertible Preferred Stock – $1,000 stated value; 4,510 shares authorized; 0 shares issued and outstanding as of both June 30, 2020 and 2019	**-**	-
Common stock - $0.001 par value; 275,000,000 shares authorized; 140,071,110 and 20,152,458 shares issued and outstanding as of June 30, 2020 and 2019, respectively	**140**	20
Additional paid-in capital	**206,931**	108,295
Accumulated other comprehensive loss	**(33)**	(31)
Accumulated deficit	**(150,420)**	(105,821)
Total iBio, Inc. Stockholders' Equity	**56,618**	2,463
Noncontrolling interest	**(11)**	(6)
Total Equity	**56,607**	2,457
Total Liabilities and Equity	**$ 94,189**	$ 30,586

The accompanying notes are an integral part of these consolidated financial statements.

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

	Years Ended June 30,	
	2020	**2019**
Revenues	**$ 1,638**	$ 2,018
Operating expenses:		
Research and development (related party of $97 and $954), net of grant income of $0 and $37	**3,213**	5,474
General and administrative (related party of $1,143 and $1,051)	**12,428**	12,332
Total operating expenses	**15,641**	17,806
Operating loss	**(14,003)**	(15,788)
Other income (expense):		
Interest expense - related party	**(2,466)**	(1,900)
Interest income	**15**	75
Royalty income	**10**	16
Total other income (expense)	**(2,441)**	(1,809)
Consolidated net loss	**(16,444)**	(17,597)
Net loss attributable to noncontrolling interest	**5**	4
Net loss attributable to iBio, Inc.	**(16,439)**	(17,593)
Deemed dividends – down round of Series A Preferred and Series B Preferred	**(21,560)**	-
Preferred stock dividends – iBio CMO Preferred Tracking Stock	**(261)**	(260)
Net loss available to iBio, Inc.	**$ (38,260)**	$ (17,853)
Comprehensive loss:		
Consolidated net loss	**$ (16,444)**	$ (17,597)
Other comprehensive loss - foreign currency translation adjustments	**(2)**	(1)
Comprehensive loss	**$ (16,446)**	$ (17,598)
Loss per common share attributable to iBio, Inc. stockholders - basic and diluted	**$ (0.61)**	$ (0.94)
Weighted-average common shares outstanding - basic and diluted	**62,795**	18,926

The accompanying notes are an integral part of these consolidated financial statements.

iBio, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
Years Ended June 30, 2020 and 2019
(In Thousands)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Noncontrolling	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Interest	Total
Balance as of July 1, 2018	12	$ -	16,040	$ 16	$ 104,408	$ (30)	$ (88,228)	$ (2)	$ 16,164
Sale of common stock	-	-	1,500	1	1,349	-	-	-	1,350
Costs to raise capital	-	-	-	-	(159)	-	-	-	(159)
Additional paid-in capital – capital contribution	-	-	-	-	2,459	-	-	-	2,459
Conversion of preferred stock to common stock	(2)	-	2,470	2	(2)	-	-	-	-
Issuance of common stock to underwriters	-	-	142	1	(1)	-	-	-	-
Share-based compensation	-	-	-	-	241	-	-	-	241
Foreign currency translation adjustment	-	-	-	-	-	(1)	-	-	(1)
Net loss	-	-	-	-	-	-	(17,593)	(4)	(17,597)
Balance as of June 30, 2019	10	$ -	20,152	$ 20	$ 108,295	$ (31)	$ (105,821)	$ (6)	$ 2,457
Balance as of July 1, 2019	**10**	**$ -**	**20,152**	**$ 20**	**$ 108,295**	**$ (31)**	**$ (105,821)**	**$ (6)**	**$ 2,457**
Sales of Series C Preferred and common stock	**5**	**-**	**40,025**	**40**	**68,045**	**-**	**-**	**-**	**68,085**
Costs to raise capital and warrant exchange	**-**	**-**	**-**	**-**	**(2,342)**	**-**	**-**	**-**	**(2,342)**
Compensation shares	**-**	**-**	**1,316**	**1**	**(1)**	**-**	**-**	**-**	**-**
Exercise of warrants	**-**	**-**	**35,000**	**35**	**7,600**	**-**	**-**	**-**	**7,635**
Exercise of stock options	**-**	**-**	**140**	**-**	**130**	**-**	**-**	**-**	**130**
Deemed dividends – down round of Series A and Series B Preferred	**-**	**-**	**-**	**-**	**21,560**	**-**	**(21,560)**	**-**	**-**
Warrant exchange and deemed dividend	**-**	**-**	**15,000**	**15**	**3,285**	**-**	**(6,600)**	**-**	**(3,300)**
Conversion of preferred stock to common stock	**(9)**	**-**	**28,438**	**29**	**(29)**	**-**	**-**	**-**	**-**
Share-based compensation	**-**	**-**	**-**	**-**	**388**	**-**	**-**	**-**	**388**
Foreign currency translation adjustment	**-**	**-**	**-**	**-**	**-**	**(2)**	**-**	**-**	**(2)**
Net loss	**-**	**-**	**-**	**-**	**-**	**-**	**(16,439)**	**(5)**	**(16,444)**
Balance as of June 30, 2020	**6**	**$ -**	**140,071**	**$ 140**	**$ 206,931**	**$ (33)**	**$ (150,420)**	**$ (11)**	**$ 56,607**

The accompanying notes are an integral part of these consolidated financial statements.

iBio, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In Thousands)

	Years Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Consolidated net loss	**$ (16,444)**	$ (17,597)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:		
Share-based compensation	**388**	241
Amortization of intangible assets	**298**	322
Amortization of finance lease right-of-use assets	**1,661**	-
Depreciation of fixed assets	**282**	1,427
Write-off of fixed assets	**-**	179
Changes in operating assets and liabilities		
Accounts receivable – trade	**22**	(22)
Work in process	**(798)**	-
Prepaid expenses and other current assets	**77**	(15)
Security deposit	**-**	1
Accounts payable	**498**	292
Accrued expenses	**140**	(82)
Contract liabilities	**531**	1,279
Net cash used in operating activities	**(13,345)**	(13,975)
Cash flows from investing activities:		
Additions to intangible assets	**(76)**	(70)
Purchases of fixed assets	**(1,078)**	(920)
Net cash used in investing activities	**(1,154)**	(990)
Cash flows from financing activities:		
Proceeds from sales of preferred and common stock	**62,363**	1,350
Proceeds from the exercise of warrants	**6,330**	-
Proceeds from the exercise of stock options	**130**	-
Costs to raise capital and warrant exchange	**(2,170)**	(159)
Proceeds from PPP Loan	**600**	-
Payments of notes payable –warrant exchange	**(1,995)**	-
Payment of finance/capital lease obligation	**(66)**	(197)
Proceeds from capital contribution	**-**	2,459
Net cash provided by financing activities	**65,192**	3,453
Effect of exchange rate changes	**(2)**	(1)
Net increase (decrease) in cash	**50,691**	(11,513)
Cash - beginning of year	**4,421**	15,934
Cash - end of year	**$ 55,112**	$ 4,421
Schedule of non-cash activities:		
Increase in ROU assets under ASC 842	**$ 7,489**	$ -
Subscription receivable for capital raise	**$ 5,549**	$ -
Costs related to subscription receivable (which is net of costs)	**$ 172**	$ -
Deemed dividends – down round of Series A Preferred and Series B Preferred	**$ 21,560**	$ -
Deemed dividend – non-cash warrant exchange	**6,600**	-
Issuances of common stock under warrant exchange	**$ 3,300**	$ -
Issuances of notes payable under warrant exchange	**$ 3,300**	$ -
Cashless exercise of warrants reducing balance owed for notes payable – warrant exchange	**$ 1,305**	$ -
Unpaid intangible assets included in accounts payable	$ -	$ 8
Intangible assets included in accounts payable in prior period, paid in current period	**$ 8**	$ 2
Unpaid fixed assets included in accounts payable	**$ 268**	$ 14
Fixed assets included in accounts payable in prior period, paid in current period	**$ -**	$ 84
Conversion of preferred stock shares into common stock shares	**$ 29**	$ 2
Compensation shares	**$ 1**	$ -
Supplemental cash flow information:		
Cash paid during the year for interest	**$ 2,372**	$ 1,903

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of Business

We are a biotechnology company and biologics contract development and manufacturing organization ("CDMO"). We apply our licensed and owned technologies to develop novel products to fight fibrotic diseases, cancers, and infectious diseases. We use our *FastPharming*® Development and Manufacturing System to increase "speed-to-clinic" for new candidates. We are also using the *FastPharming* System to create proteins and bioinks for research and further manufacturing uses in a variety of research and development ("R&D") applications, including 3D-bioprinting. In addition, we make the *FastPharming* System available to clients on a fee-for-service basis for the production of proteins.

During the year ended June 30, 2020, we operated in two segments: (i) our CDMO segment, operated via our subsidiary iBio CDMO LLC ("iBio CDMO"), and (ii) our biologics development and licensing activities, conducted within iBio, Inc. In the past, our primary focus was the CDMO business, pursuant to which iBio CDMO provided manufacturing services to collaborators and third-party customers as well as to us, for our own product development purposes. However, during the second half of 2020 and subsequent to year end, we shifted our primary focus to our biologics development programs, including new vaccines and therapeutics.

Our current platforms and programs include: (i) CDMO services using our licensed and owned *FastPharming* Technologies and *Glycaneering*™ Services; (ii) the development of therapeutics, for which we intend to conduct preclinical and clinical trials; (iii) the development of vaccines, for which we intend to conduct preclinical and clinical trials, and (iv) the production of proteins for research and further manufacturing use in 3D-bioprinting and other applications. We are developing a portfolio of technologies, products, and services driven by the following platforms and programs, which we intend to use individually, and in combination:

- **CDMO Services**
  - Process development and manufacturing of protein products in hydroponically-grown, transiently-transfected plants, (typically *Nicotiana benthamiana,* a relative of the tobacco plant) using our proprietary expression technologies, *Glycaneering* Services, and production know-how (the *FastPharming* System), deployed in our 130,000 square-foot manufacturing facility in Bryan, Texas.
  - "Factory Solutions" for the clients who seek to insource biologics manufacturing using the *FastPharming* System and instead of outsourcing production to iBio CDMO.
- **Therapeutics**
  - Treatments for fibrotic diseases, including a fusion of the endostatin-derived E4 antifibrotic peptide to the hinge and heavy chain of human IgG1 ("IBIO-100", formerly described as "CFB-03") for systemic scleroderma (for which we have received orphan drug designation), idiopathic pulmonary fibrosis, and related conditions.
  - An ACE2-Fc fusion protein as a treatment for COVID-19 and, prospectively, other diseases emanating from the *Coronaviridae* family, in-licensed from Planet Biotechnology, Inc.
- **Vaccines**
  - A novel virus-like particle antigen being designed for use in a vaccine candidate targeting the SARS-CoV-2 virus ("IBIO-200").
  - The lichenase ("*LicKM*™")-subunit vaccine for COVID-19 ("IBIO-201").
  - An E2 antigen, in combination with a selected adjuvant, for vaccination of pigs against classical swine fever ("IBIO-400").
- **Research & Bioprocess Products**
  - Protein scaffolds for use as bioinks in the development of 3D-bioprinted tissues and organs.
  - Cytokines and growth factors for cell culture applications.
  - Biomaterials for a range of life science research, development, and bioprocessing applications.

Our Platforms and Programs

CDMO Services

Our contract development and manufacturing services include:

Process Development	Feasibility assessment and development of manufacturing processes using the *FastPharming* Technology for optimized gene expression and purification parameters to meet client specifications for their active pharmaceutical ingredients ("APIs"). Product optimization via our *Glycaneering* Services that may be used to enhance the quality and performance of therapeutic proteins via plant-based glycosylation controls.
Manufacturing	Biologics production using the *FastPharming* System to deliver custom biologics for clinical trials.
Fill / Finish	Aseptic vial and bottle filling and finishing services with in-line labelling that provides serialization capability for greater quality assurance.
BioAnalytics	Method development and validation with expertise in protein characterization using mass spectrometry.

iBio was established as a public company in August 2008 as the result of a spinoff from Integrated BioPharma, Inc and operates in two business segments. iBio's wholly-owned and majority-owned subsidiaries as follows:

iBio CDMO (originally named iBio CMO LLC) – iBio CDMO is a Delaware limited liability company formed on December 16, 2015 as iBio CMO, LLC to develop and manufacture plant-made pharmaceuticals and provide related services to clients. Effective July 1, 2017, iBio CMO changed its name to iBio CDMO. As of December 31, 2015, the Company owned 100% of iBio CDMO. On January 13, 2016, the Company entered into a contract manufacturing joint venture with an affiliate of Eastern Capital Limited ("Eastern"), a stockholder of the Company (the "Eastern Affiliate"). The Eastern Affiliate contributed $15 million in cash for a 30% interest in iBio CDMO. The Company retained a 70% interest in iBio CDMO and contributed a royalty-bearing license which grants iBio CDMO a non-exclusive license to use the Company's proprietary technologies for research purposes and an exclusive U.S. license for manufacturing purposes. The Company retained the exclusive right to grant product licenses to those who wish to sell or distribute products made using the Company's technologies.

On February 23, 2017, the Company entered into an exchange agreement with the Eastern Affiliate, pursuant to which the Company acquired substantially all of the interest in iBio CDMO held by the Eastern Affiliate in exchange for one share of the Company's iBio CMO Preferred Tracking Stock, par value $0.001 per share. After giving effect to the transaction, the Company owns 99.99% of iBio CDMO. See Note 14 - Stockholders' Equity for a further discussion. At any time, at our election or the election of the Eastern Affiliate, the outstanding share of iBio CMO Preferred Tracking Stock may be exchanged for 29,990,000 units of limited liability company interests of iBio CDMO. Following such exchange, we would own a 70% interest in iBio CDMO and the Eastern Affiliate would own a 30% interest.

iBio CDMO's operations take place in Bryan, Texas in a facility controlled by another affiliate of Eastern (the "Second Eastern Affiliate") as sublandlord. The facility is a 130,000-square foot Class A life sciences building located on land owned by the Texas A&M system, designed and equipped for plant-made manufacture of biopharmaceuticals. The Second Eastern Affiliate granted iBio CDMO a 34-year lease (the "Sublease") for the facility as well as certain equipment (see Note 13 – Finance Lease Obligations). iBio CDMO commenced commercial operations in January 2016. iBio CDMO expects to operate on the basis of three parallel lines of business: (1) Development and manufacturing of third-party products; (2) Development and production of iBio's proprietary products; and (3) Commercial technology transfer services including facility design, as needed.

IBIO DO BRASIL BIOFARMACÊUTICA LTDA ("iBio Brazil") – iBio Brazil is a subsidiary organized in Brazil in which the Company has a 99% interest. iBio Brazil was formed to manage and expand the Company's business activities in Brazil. The activities of iBio Brazil are intended to include coordination and expansion of the Company's existing relationship with Fundacao Oswaldo Cruz/Fiocruz ("Fiocruz") beyond the Yellow Fever Vaccine program (see Note 9 – Significant Vendors) and development of additional products with private sector participants for the Brazilian market. iBio Brazil commenced operations during the first quarter of the fiscal year ended June 30, 2015.

iBio Manufacturing LLC ("iBio Manufacturing") – iBio Manufacturing, a wholly-owned subsidiary, is a Delaware limited liability company formed in November 2015. iBio Manufacturing has not commenced any activities to date.

2. Basis of Presentation

Since our spin-off from Integrated BioPharma, Inc. in August 2008, we have incurred significant losses and negative cash flows from operations. The Company's net loss was approximately $16.4 million and $17.6 million for the years ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the Company's accumulated deficit was $150.4 million and it had cash used in operating activities of $13.3 million for the year ended June 30, 2020. As of October 8, 2020, cash and marketable securities exceeded $83 million which we expect to support the Company's activities through fiscal year 2022. In the short-term, we are seeking funding to support our activities beyond such date and accelerate our growth initiatives and have engaged an investment banking firm to assist in this regard.

The following equity transactions occurred during Fiscal 2020:

1. On October 29, 2019, the Company closed on an underwritten public offering with total net proceeds of $4.5 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company.

2. On March 19, 2020, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company, pursuant to which Lincoln Park agreed to purchase from the Company up to an aggregate of $50,000,000 of the Company's common stock (subject to certain limitations) from time to time over the 36-month term of the agreement (the "Lincoln Park March 2020 Purchase Agreement"). As of June 30, 2020, Lincoln Park has acquired 16.8 million shares of the Company's common stock for gross proceeds of approximately $18.4 million. From July 1, 2020 through the filing date of this report, Lincoln Park has acquired 2.7 million shares of the Company's common stock for gross proceeds of approximately $6.8 million. No further sales of shares of common stock will be made since we terminated the Lincoln Park March 2020 Purchase Agreement effective July 27, 2020.

3. In Fiscal 2020, the Company received proceeds of $6.3 million from the exercise of various warrants.

4. On May 13, 2020, the Company entered into a purchase agreement (the "Lincoln Park May 2020 Purchase Agreement"), pursuant to which the Company agreed to sell to Lincoln Park and Lincoln Park agreed to purchase 1,000,000 shares of the Company's common stock at a price of $1.09 per share for an aggregate purchase price of $1.1 million.

5. On June 17, 2020 as amended on July 29, 2020, the Company entered into an equity distribution agreement with UBS Securities, LLC ("UBS") as sales agent pursuant to which the Company may sell from time to time shares of its common stock through UBS, for the sale of up to $72,000,000 of shares of the Company's common stock. This ATM facility included the remaining portion of the Lincoln Park facility. As of June 30, 2020, the Company has issued 19.8 million shares of the Company's common stock for net proceeds of approximately $42.2 million. From July 1, 2020 through the filing date of this report, the Company issued 8.6 million shares of the Company's common stock for net proceeds of approximately $24.6 million.

See Note 14 – Stockholders' Equity for additional information.

In the past, the history of significant losses, the negative cash flow from operations, the limited cash resources on hand and the dependence by the Company on its ability – about which there was certainty – to obtain additional financing to fund its operations after the current cash resources are exhausted raised substantial doubt about the Company's ability to continue as a going concern. Based on the total cash on hand of approximately $55.1 million as of June 30, 2020, combined with subsequent purchases of the Company's common stock through the date of the filing of this report totaling approximately $31.4 million, we believe the Company has adequate cash on hand to support the Company's activities through fiscal year 2022.

The Company has historically financed its activities through the sale of common stock and warrants. Through June 30, 2020, the Company has dedicated most of its financial resources to research and development, including the development and validation of its own technologies and the development of a proprietary therapeutic product against fibrosis based upon those technologies, advancing its intellectual property, the build-out and recommissioning of its CDMO facility, and general and administrative activities.

As of June 30, 2020, the Company has not completed development of or commercialized any vaccine or therapeutic product candidates. As such, the Company expects to continue to incur significant expenses and operating losses for at least the next year. The Company anticipates that its expenses and losses will increase substantially if the Company:

- initiates clinical trials of its product candidates;
- continues the research and development of its product candidates;
- seeks to discover additional product candidates; and
- adds operational, financial and management information systems and personnel, including personnel to support its product development and manufacturing efforts.

To become and remain profitable, the Company must succeed in commercializing its technologies, alone or with its licensees, the service offerings provided by its CDMO facility, and in developing and eventually commercializing products that generate significant revenue. In addition, profitability will depend on continuing to attract and retain customers for the development, manufacturing and technology transfer services offered by the Company.

On June 26, 2018, the Company closed on an underwritten public offering with total gross proceeds of approximately $16.0 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company. The securities offered by the Company consisted of (i) 4,350,000 shares of Common Stock at $0.90 per share, (ii) 6,300 shares of Series A Convertible Preferred Stock ("Series A Preferred"), and (iii) 5,785 shares of Series B Convertible Preferred Stock. The Company granted the underwriters a 45-day option to purchase up to an additional 2,666,666 shares of common stock to cover over-allotments, if any. On July 12, 2018, the Company received approximately $1.35 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company, from the proceeds of the sale of 1,500,000 over-allotment shares of Common Stock purchased at $0.90 by the underwriter during the 45-day provision. See Note 14 – Stockholders' Equity for additional information.

In July 2019, iBio entered into a Master Manufacturing Services and Supply Agreement ("MSA") with Lung Biotechnology PBC ("Lung Bio"), a subsidiary of United Therapeutics Corporation, to produce recombinant human collagen-based bioink for 3D-bioprinted organ transplants. iBio will collaborate with Lung Bio to scale-up production of rhCollagen in tobacco plants using iBio's *FastPharming*® System. Under the MSA, the initial work to be performed by iBio involves the development of a scalable purification process for rhCollagen, as well as cGMP supply of the material for clinical trials. During the quarter ended September 30, 2019, iBio received a prepayment of approximately $1.6 million from Lung Bio, $1.0 million of which was allocated to the purchase of capital expenditures per the MSA and $620,000 allocated to the performance of related contracted services. The $1.6 million was recorded as a contract liability on the balance sheet. In Fiscal 2020, the Company recognized approximately $46,000 of the contract liability amount related to Lung Bio as revenue.

In addition, in June 2018, iBio established a strategic commercial relationship with CC-Pharming Ltd. of Beijing, China ("CC-Pharming") under a Master Joint Development Agreement for the development of products utilizing the *FastPharming* Technologies and the establishment of manufacturing facilities for the Chinese biopharmaceutical market via iBio's Factory Solutions Services. In August 2019, we licensed our rituximab biosimilar/biobetter candidates to CC-Pharming for the China territory, and also provided a research license to the *FastPharming* Technologies for use in the evaluation of reagents for research, diagnostic, bioprocess, and cosmetic applications. On February 6, 2020, the Company entered into a statement of work to develop and test a new CC-Pharming 2019-nCoV vaccine to be manufactured using iBio's *FastPharming* System. During the quarter ended September 30, 2018, iBio received prepayments of approximately $3.1 million from CC-Pharming which it recorded as a contract liability on its balance sheet. In Fiscal 2019, the Company recognized approximately $1.8 million of the contract liability amounts related to CC-Pharming as revenue. In Fiscal 2020, the Company recognized the remaining $1.3 million as revenue.

In November 2018, the Company received a capital contribution from the Eastern Affiliate of approximately $2.5 million for working capital purposes.

The Company plans to fund its future business operations using cash on hand, through proceeds from the sale of additional equity or other securities, and through proceeds realized in connection with the commercialization of its technologies and proprietary products, license and collaboration arrangements and the operation of our subsidiary, iBio CDMO.

As a result of the impact of the COVID-19 pandemic crisis, the Company ascertained that certain risks associated with further COVID-19 developments may adversely impact the Company's capital and financial resources, including the Company's overall liquidity position and outlook, any changes, or reasonably expected changes, to the Company's cost of, or access to, capital and funding sources, and any material impact to its sources or uses of cash. Although the Company does not anticipate any negative current impact, the risk exists that further COVID-19 developments may negatively impact the Company's financial condition and restrict the availability of liquidity for its operational needs.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated as part of the consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. These estimates include liquidity assertions, the valuation of intellectual property, legal and contractual contingencies and share-based compensation. Although management bases its estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances, actual results could differ from these estimates.

Accounts Receivable

Accounts receivable are reported at their outstanding unpaid principal balances net of allowances for uncollectible accounts. The Company provides for allowances for uncollectible receivables based on management's estimate of uncollectible amounts considering age, collection history, and any other factors considered appropriate. The Company writes off accounts receivable against the allowance for doubtful accounts when a balance is determined to be uncollectible. At June 30, 2020 and 2019, the Company determined that an allowance for doubtful accounts was not needed.

Revenue Recognition

The Company accounts for its revenue recognition under Accounting Standards Update ("ASU") No. 2014-09, "*Revenue from Contracts with Customers (Topic 606)*" ("ASU 2014-09") and other associated standards. Under this new standard, the Company recognizes revenue when a customer obtains control of promised services or goods in an amount that reflects the consideration to which the Company expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts.

The Company's contract revenue consists primarily of amounts earned under contracts with third-party customers and reimbursed expenses under such contracts. The Company analyzes its agreements to determine whether the elements can be separated and accounted for individually or as a single unit of accounting. Allocation of revenue to individual elements that qualify for separate accounting is based on the separate selling prices determined for each component, and total contract consideration is then allocated pro rata across the components of the arrangement. If separate selling prices are not available, the Company will use its best estimate of such selling prices, consistent with the overall pricing strategy and after consideration of relevant market factors.

In general, the Company applies the following steps when recognizing revenue from contracts with customers: (i) identify the contract, (ii) identify the performance obligations, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations and (v) recognize revenue when a performance obligation is satisfied. The nature of the Company's contracts with customers generally fall within the three key elements of the Company's business plan: CDMO Facility Activities; Product Candidate Pipeline, and Facility Design and Build-out / Technology Transfer services.

Recognition of revenue is driven by satisfaction of the performance obligations using one of two methods: revenue is either recognized over time or at a point in time. Contracts containing multiple performance obligations classify those performance obligations into separate units of accounting either as standalone or combined units of accounting. For those performance obligations treated as a standalone unit of accounting, revenue is generally recognized based on the method appropriate for each standalone unit. For those performance obligations treated as a combined unit of accounting, revenue is generally recognized as the performance obligations are satisfied, which generally occurs when control of the goods or services have been transferred to the customer or client or once the client or customer is able to direct the use of those goods and / or services as well as obtaining substantially all of its benefits. As such, revenue for a combined unit of accounting is generally recognized based on the method appropriate for the last delivered item but due to the specific nature of certain project and contract items, management may determine an alternative revenue recognition method as appropriate, such as a contract whereby one deliverable in the arrangement clearly comprises the overwhelming majority of the value of the overall combined unit of accounting. Under this circumstance, management may determine revenue recognition for the combined unit of accounting based on the revenue recognition guidance otherwise applicable to the predominant deliverable.

The Company generates (or may generate in the future) contract revenue under the following types of contracts:

Fixed-Fee

Under a fixed-fee contract, the Company charges a fixed agreed upon amount for a deliverable. Fixed-fee contracts have fixed deliverables upon completion of the project. Typically, the Company recognizes revenue for fixed-fee contracts after projects are completed, delivery is made and title transfers to the customer, and collection is reasonably assured.

Revenue can be recognized either 1) over time or 2) at a point in time. In 2020, $147,000 was recognized over time and 1,491,000 was recognized at a point in time. The comparative amounts for 2019 were $1,848,000 recognized over time and $170,000 recognized at a point in time.

Time and Materials

Under a time and materials contract, the Company charges customers an hourly rate plus reimbursement for other project specific costs. The Company recognizes revenue for time and material contracts based on the number of hours devoted to the project multiplied by the customer's billing rate plus other project specific costs incurred.

Grant Income

Grants are recognized as income when all conditions of such grants are fulfilled or there is a reasonable assurance that they will be fulfilled. Grant income is classified as a reduction of research and development expenses. In 2020 and 2019, grant income amounted to approximately $0 and $37,000, respectively.

Contract Assets

A contract asset is an entity's right to payment for goods and services already transferred to a customer if that right to payment is conditional on something other than the passage of time. Generally, an entity will recognize a contract asset when it has fulfilled a contract obligation but must perform other obligations before being entitled to payment.

Contract assets consist primarily of the cost of project contract work performed by third parties whereby the Company expects to recognize any related revenue at a later date, upon satisfaction of the contract obligations. At both June 30, 2020 and 2019, contract assets were $0.

Contract Liabilities

A contract liability is an entity's obligation to transfer goods or services to a customer at the earlier of (1) when the customer prepays consideration or (2) the time that the customer's consideration is due for goods and services the entity will yet provide. Generally, an entity will recognize a contract liability when it receives a prepayment.

Contract liabilities consist primarily of consideration received, usually in the form of payment, on project work to be performed whereby the Company expects to recognize any related revenue at a later date, upon satisfaction of the contract obligations. At both June 30, 2020 and 2019, contract liabilities were $1,810,000 and $1,279,000, respectively. The Company recognized revenue of $1,279,000 in 2020 that was included in the contract liabilities balance as of June 30, 2019.

Leases

Effective July 1, 2019, the Company adopted ASU 2016-02, "*Leases (Topic 842)*" ("ASU 2016-02") ("ASC 842") and other associated standards using the modified retrospective approach for all leases entered into before the effective date. The new standard establishes a right-of-use ("ROU") model requiring a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months and classified as either an operating or finance lease. The adoption of ASC 842 had a significant effect on the Company's balance sheet, resulting in an increase in non-current assets and both current and non-current liabilities. The adoption of ASC 842 had no impact on retained earnings as the assets recognized under the Sublease and the associated lease obligation were accounted for as a capital lease under Topic 840. The Company did not have any operating leases, therefore there was no change in accounting treatment required. For comparability purposes, the Company will continue to comply with prior disclosure requirements in accordance with the then existing lease guidance under Topic 840 as prior periods have not been restated.

As the Company elected to adopt ASC 842 at the beginning of the period of adoption, the Company recorded the ROU and finance lease obligation as follows:

1. ROU measured at the carrying amount of the leased assets under Topic 840.

2. Finance lease liability measured at the carrying amount of the capital lease obligation under Topic 840 at the beginning of the period of adoption.

The Company elected the package of practical expedients as permitted under the transition guidance, which allowed it: (1) to carry forward the historical lease classification; (2) not to reassess whether expired or existing contracts are or contain leases; and, (3) not to reassess the treatment of initial direct costs for existing leases.

In accordance with ASC 842, at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present and the classification of the lease including whether the contract involves the use of a distinct identified asset, whether the Company obtains the right to substantially all the economic benefit from the use of the asset, and whether the Company has the right to direct the use of the asset. Leases with a term greater than one year are recognized on the balance sheet as ROU assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less under practical expedient in paragraph ASC 842-20-25-2. For contracts with lease and non-lease components, the Company has elected not to allocate the contract consideration and to account for the lease and non-lease components as a single lease component.

The lease liability and the corresponding ROU assets were recorded based on the present value of lease payments over the expected remaining lease term. The implicit rate within our capital lease was determinable and, therefore, used at the adoption date of ASC 842 to determine the present value of lease payments under the finance lease.

An option to extend the lease is considered in connection with determining the ROU asset and lease liability when it is reasonably certain we will exercise that option. An option to terminate is considered unless it is reasonably certain we will not exercise the option.

For periods prior to the adoption of ASC 842, the Company recorded interest expense based on the amortization of the capital lease obligation. The expense recognition for finance leases under Topic 842 is substantially consistent with prior guidance for capital leases. As a result, there are no significant differences in our results of operations presented.

The impact of the adoption of ASC 842 on the balance sheet was (in thousands):

	As reported June 30, 2019	Adoption of ASC 842	Balance July 1, 2019
Finance lease right-of-use assets	$ -	$ 7,489	$ 7,489
Total assets	$ 30,586	$ 7,489	$ 38,075
Finance lease obligation - current portion	$ 213	$ (141)	$ 72
Finance lease obligation - net of current portion	$ 24,671	$ 7,630	$ 32,301
Total liabilities	$ 28,129	$ 7,489	$ 35,618
Total liabilities and stockholders' equity	$ 30,586	$ 7,489	$ 38,075

The impact of the adoption of ASC 842 on the Statement of Operations for the year ended June 30, 2020 was (in thousands):

	Prior to Adoption	Adoption of ASC 842	Balance
Total revenues	$ 1,638	$ -	$ 1,638
Operating expenses	$ 15,171	$ 470(1)	$ 15,641
Operating loss	$ (13,533)	$ (470)	$ (14,003)
Other income (expense)	$ (1,860)	$ (581)(2)	$ (2,441)
Consolidated net loss	$ (15,393)	$ (1,051)	$ (16,444)

(1) Excess of the amortization of finance lease ROU's over the depreciation of capital lease assets that would have occurred under ASC 840.

(2) Excess of the interest expense related to the finance lease obligation over the interest expense of the capital lease obligation that would have been incurred under ASC 840.

Work in Process

Work in process consists primarily of the cost of labor and other overhead incurred on contracts that have not been completed. Work in process amounted to $798,000 and $0 as of June 30, 2020 and 2019, respectively.

Research and Development

The Company accounts for research and development costs in accordance with the FASB ASC 730-10, "*Research and Development*" ("ASC 730-10"). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved.

Right-of-Use Assets

Assets held under the terms of finance (capital) leases are amortized on a straight-line basis over the terms of the leases or the economic lives of the assets. Obligations for future lease payments under finance (capital) leases are shown within liabilities and are analyzed between amounts falling due within and after one year. See Note 6 - Finance Lease ROU's and Note 13 - Finance Lease Obligation for additional information.

Fixed Assets

Fixed assets are stated at cost net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets ranging from three to fifteen years.

Intangible Assets

The Company accounts for intangible assets at their historical cost and records amortization utilizing the straight-line method based upon their estimated useful lives. Patents are amortized over a period of 10 years and other intellectual property is amortized over a period from 16 to 23 years. The Company reviews the carrying value of its intangible assets for impairment whenever events or changes in business circumstances indicate the carrying amount of such assets may not be fully recoverable. Evaluating for impairment requires judgment, and recoverability is assessed by comparing the projected undiscounted net cash flows of the assets over the remaining useful life to the carrying amount. Impairments, if any, are based on the excess of the carrying amount over the fair value of the assets. There were no impairment charges for the years ended June 30, 2020 and 2019.

Foreign Currency

The Company accounts for foreign currency translation pursuant to FASB ASC 830, "*Foreign Currency Matters.*" The functional currency of iBio Brazil is the Brazilian Real. Under FASB ASC 830, all assets and liabilities are translated into United States dollars using the current exchange rate at the end of each fiscal period. Revenues and expenses are translated using the average exchange rates prevailing throughout the respective periods. All transaction gains and losses from the measurement of monetary balance sheet items denominated in Reals are reflected in the statement of operations as appropriate. Translation adjustments are included in accumulated other comprehensive loss. For both 2020 and 2019, any translation adjustments were considered immaterial and did not have a significant impact on the Company's consolidated financial statements.

Share-based Compensation

The Company recognizes the cost of all share-based payment transactions at fair value. Compensation cost, measured by the fair value of the equity instruments issued, adjusted for estimated forfeitures, is recognized in the financial statements as the respective awards are earned over the performance period. The Company uses historical data to estimate forfeiture rates.

The impact that share-based payment awards will have on the Company's results of operations is a function of the number of shares awarded, the trading price of the Company's stock at the date of grant or modification, the vesting schedule and forfeitures. Furthermore, the application of the Black-Scholes option pricing model employs weighted-average assumptions for expected volatility of the Company's stock, expected term until exercise of the options, the risk-free interest rate, and dividends, if any, to determine fair value.

Expected volatility is based on historical volatility of the Company's common stock; the expected term until exercise represents the weighted-average period of time that options granted are expected to be outstanding giving consideration to vesting schedules and the Company's historical exercise patterns; and the risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company has not paid any dividends since its inception and does not anticipate paying any dividends for the foreseeable future, so the dividend yield is assumed to be zero. In addition, the Company estimates forfeitures at each reporting period rather than electing to record the impact of such forfeitures as they occur. See Note 16 – Share-Based Compensation for additional information.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be realized. The effect of a change in tax rates or laws on deferred tax assets and liabilities is recognized in operations in the period that includes the enactment date of the rate change. A valuation allowance is established to reduce the deferred tax assets to the amounts that are more likely than not to be realized from operations.

Tax benefits of uncertain tax positions are recognized only if it is more likely than not that the Company will be able to sustain a position taken on an income tax return. The Company has no liability for uncertain tax positions as of June 30, 2020 and 2019. Interest and penalties, if any, related to unrecognized tax benefits would be recognized as income tax expense. The Company does not have any accrued interest or penalties associated with unrecognized tax benefits, nor was any significant interest expense recognized during 2020 and 2019.

Concentrations of Credit Risk

Cash

The Company maintains principally all cash balances in one financial institution which, at times, may exceed the amount insured by the Federal Deposit Insurance Corporation. The exposure to the Company is solely dependent upon daily bank balances and the strength of the financial institution. The Company has not incurred any losses on these accounts. At June 30, 2020 and 2019, amounts in excess of insured limits were approximately $54,680,000 and $3,924,000, respectively.

Revenue

CC-Pharming accounted for approximately 77% and 92% of revenues in 2020 and 2019, respectively.

Disclosure of Prior Period Financial Statement Error

In connection with the preparation of our consolidated financial statements, the Company identified an error related to the omission from the financial statements for the three and nine months ended March 31, 2020 of a sale of shares of common stock under its equity distribution agreement that was initiated during the period ended March 31, 2020 but which settled subsequent to the end of the quarter. We note that this sale of shares was disclosed in the notes section of the Form 10-Q for the third quarter of fiscal year 2020. The Company assessed the materiality of this error in accordance with SAB No. 99, "Materiality," and SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements," both quantitatively and qualitatively and determined that restatement was not required for the period, but has elected to correct the error in light of its impact on its balance sheet. Accordingly, the Company has revised previously reported financial information for such error, as previously disclosed in our Quarterly Report on Form 10-Q for the third quarter of fiscal 2020. A summary of revisions to certain previously reported financial information presented herein for comparative purposes is included in Note 24.

4. Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, "*Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*" ("ASU 2016-13"), which requires an entity to assess impairment of its financial instruments based on its estimate of expected credit losses. Since the issuance of ASU 2016-13, the FASB released several amendments to improve and clarify the implementation guidance. In November 2019, the FASB issued ASU 2019-10, "*Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*", which amended the effective date of the various topics. As the Company is a smaller reporting company, the provisions of ASU 2016-13 and the related amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 (quarter ending September 30, 2023 for the Company). Entities are required to apply these changes through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company will evaluate the impact of ASU 2016-13 on the Company's consolidated financial statements in a future period closer to the date of adoption.

Effective July 1, 2018, the Company adopted ASU 2017-09, "*Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting"* ("ASU 2017-09") which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The adoption of ASU 2017-09 did not have a significant impact on the Company's consolidated financial statements.

Effective April 1, 2018, the Company adopted ASU 2017-11, "*Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)"* ("ASU 2017-11"). The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with ASC 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in ASC 470-20, "*Debt—Debt with Conversion and Other Options*"), including related EPS guidance (in ASC 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of ASC 480 that now are presented as pending content in the codification, to a scope exception. Those amendments do not have an accounting effect. As a result of the adoption of ASU 2017-11, the Company classified the proceeds received from the sale of its preferred stock as equity (see Note 14 – Stockholders' Equity).

Effective July 1, 2019, the Company adopted ASU 2018-07, "*Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*" ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The adoption of ASU 2018-07 did not have a significant impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, "*Simplifying the Accounting for Income Taxes*" ("ASU 2019-12") to reduce the cost and complexity in accounting for income taxes. ASU 2019-12 removes certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also amends other aspects of the guidance to help simplify and promote consistent application of U.S. GAAP. The guidance is effective for fiscal years and for interim periods within those fiscal years, beginning after December 15, 2020 (quarter ending September 30, 2021 for the Company), with early adoption permitted. An entity that elects early adoption must adopt all the amendments in the same period. Most amendments within ASU 2019-12 are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. The Company is currently evaluating the impact of ASU 2019-12 on the Company's consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting standard if currently adopted would have a material effect on the accompanying consolidated financial statements. Most of the newer standards issued represent technical corrections to the accounting literature or application to specific industries which have no effect on the Company's consolidated financial statements.

5. Financial Instruments and Fair Value Measurement

The carrying values of cash, accounts receivable and accounts payable in the Company's consolidated balance sheets approximated their fair values as of June 30, 2020 and 2019 due to their short-term nature. The carrying values of the finance (capital) lease obligation approximated its fair value at June 30, 2020 and 2019 as the interest rate used to discount the lease payments approximated market.

6. Finance Lease ROU's

As discussed above, the Company adopted ASC 842 effective July 1, 2019 using the modified retrospective approach for all leases entered into before the effective date.

iBio CDMO is leasing its facility in Bryan, Texas as well as certain equipment from the Second Eastern Affiliate under the Sublease. See Note 13 – Finance Lease Obligation for more details of the terms of the Sublease.

The economic substance of the Sublease is that the Company is financing the acquisition of the facility and equipment. As the Sublease involves real estate and equipment, the Company separated the equipment component and accounted for the facility and equipment as if each was leased separately.

The following table summarizes by category the gross carrying value and accumulated amortization of finance lease ROU (in thousands):

	June 30, 2020	June 30, 2019
ROU - Facility	**$ 25,761**	$ -
ROU - Equipment	**7,728**	-
	33,489	-
Accumulated amortization	**(5,873)**	-
Net finance lease ROU	**$ 27,616**	$ -

Amortization expense was approximately $1,661,000 for the year in 2020.

7. Fixed Assets

As discussed above, the Company adopted ASC 842. As such, assets formerly classified as "under capital lease" are now classified as finance lease ROU assets. See Note 6 – Finance Lease ROU's above.

The following table summarizes by category the gross carrying value and accumulated depreciation of fixed assets (in thousands):

	June 30, 2020	June 30, 2019
Facility improvements	**$ 1,465**	$ 1,449
Medical equipment	**1,760**	1,260
Office equipment and software	**398**	231
Construction in progress	**787**	138
Facility under capital lease	**-**	20,000
Equipment under capital lease	**-**	6,000
	4,410	29,078
Accumulated depreciation – assets under capital lease	**-**	(4,212)
Accumulated depreciation	**(753)**	(486)
Net fixed assets	**$ 3,657**	$ 24,380

Depreciation expense was approximately $282,000 and $1,427,000 in 2020 and 2019, respectively.

In addition, $179,000 of fixed assets were written off in 2019 related to items previously capitalized that have subsequently been removed from service and were included in general and administrative expenses.

8. Intangible Assets

The Company has two categories of intangible assets – intellectual property and patents. Intellectual property consists of all technology, know-how, data, and protocols for producing targeted proteins in plants and related to any products and product formulations for pharmaceutical uses and for other applications. Intellectual property includes, but is not limited to, certain technology for the development and manufacture of novel vaccines and therapeutics for humans and certain veterinary applications acquired in December 2003 from Fraunhofer USA Inc., acting through its Center for Molecular Biotechnology ("Fraunhofer"), pursuant to a Technology Transfer Agreement, as amended (the "TTA"). The Company designates such technology further developed and acquired from Fraunhofer as *iBioLaunch*™ or *LicKM*™ or *FastPharming*® technology. The value on the Company's books attributed to patents owned or controlled by the Company is based only on payments for services and fees related to the protection of the Company's patent portfolio. The intellectual property also includes certain trademarks.

In January 2014, the Company entered into a license agreement with a U.S. university whereby iBio acquired exclusive worldwide rights to certain issued and pending patents covering specific candidate products for the treatment of fibrosis (the "Licensed Technology"). The license agreement provides for payment by the Company of a license issue fee, annual license maintenance fees, reimbursement of prior patent costs incurred by the university, payment of a milestone payment upon regulatory approval for sale of a first product, and annual royalties on product sales. In addition, the Company has agreed to meet certain diligence milestones related to product development benchmarks. As part of its commitment to the diligence milestones, the Company successfully commenced production of a plant-made peptide comprising the Licensed Technology before March 31, 2014. The next milestone – filing a New Drug Application with the FDA or foreign equivalent covering the Licensed Technology ("IND") – initially became due on December 1, 2015, and on August 11, 2016, the agreement was amended and subsequent six-month extensions have been automatically granted extending the due date until December 31, 2017, at which time, the Company and the university agreed to set a new milestone schedule and are currently undergoing an analysis based on new data and revised forecasted timelines.

The Company accounts for intangible assets at their historical cost and records amortization utilizing the straight-line method based upon their estimated useful lives. Patents are amortized over a period of 10 years and other intellectual property is amortized over a period from 16 to 23 years. The Company reviews the carrying value of its intangible assets for impairment whenever events or changes in business circumstances indicate the carrying amount of such assets may not be fully recoverable. Evaluating for impairment requires judgment, and recoverability is assessed by comparing the projected undiscounted net cash flows of the assets over the remaining useful life to the carrying amount. Impairments, if any, are based on the excess of the carrying amount over the fair value of the assets. There were no impairment charges during the years ended June 30, 2020 and 2019.

The following table summarizes by category the gross carrying value and accumulated amortization of intangible assets (in thousands):

	June 30, 2020	June 30, 2019
Intellectual property – gross carrying value	**$ 3,100**	$ 3,100
Patents – gross carrying value	**2,628**	2,560
	5,728	5,660
Intellectual property – accumulated amortization	**(2,555)**	(2,399)
Patents – accumulated amortization	**(2,029)**	(1,887)
	(4,584)	(4,286)
Net intangible assets	**$ 1,144**	$ 1,374

Amortization expense, included in general and administrative expenses, was approximately $298,000 and $322,000 for 2020 and 2019, respectively. The weighted-average remaining life for intellectual property and patents at June 30, 2020 was approximately 3.5 years and 6.2 years, respectively. The estimated annual amortization expense for the next five years and thereafter is as follows (in thousands):

For the Year Ending June 30,	
2021	$ 280
2022	266
2023	252
2024	156
2025	62
Thereafter	128
Total	$ 1,144

9. Significant Vendors

Novici Biotech, LLC
In January 2012, the Company entered into an agreement with Novici Biotech, LLC ("Novici") in which iBio's President is a minority stockholder. Novici performs laboratory feasibility analyses of gene expression, protein purification and preparation of research samples. In addition, the Company and Novici collaborate on the development of new technologies and product candidates for exclusive worldwide commercial use by the Company. The accounts payable balance includes amounts due to Novici of approximately $0 and $65,000 at June 30, 2020 and 2019, respectively. Research and development expenses related to Novici were approximately $97,000 and $954,000 in 2020 and 2019, respectively.

10. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2020	June 30, 2019
Rent and real estate taxes – related party (see Note 17)	**$ 295**	$ 383
Interest – related party (see Note 17)	**410**	316
Salaries and benefits	**231**	166
Other accrued expenses	**169**	100
Total accrued expenses	**$ 1,105**	$ 965

11. Notes Payable – Warrant Exchange

As part of the Warrant Amendment and Exchange Agreement dated February 20, 2020 (see Note 14 – Stockholders' Equity for additional information), the Company issued promissory notes in the aggregate principal amount of $3,300,000. The notes did not bear interest and were payable in full on the earlier to occur of (i) August 20, 2020, or (ii) the completion of an underwritten offering of securities by the Company resulting in gross proceeds of at least $10 million. In addition, the Company was required to make payments upon any and all cash exercises of the noteholders' warrants on a dollar for dollar basis for all amounts paid pursuant to such warrant exercises. At June 30, 2020, the notes payable were repaid.

12. Notes Payable – PPP Loan

On April 16, 2020, the Company received $600,000 related to its filing under the Paycheck Protection Program and Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The payment terms of the note are as follows:

1. No payments during the deferral period, which is defined as the six-month period beginning on the date of the note of April 9, 2020.

2. Commencing one month after the expiration of the deferral period, and continuing on the same day of each month thereafter until the maturity date, the Company shall pay to JPMorgan Chase Bank, N.A. (the "Lender"), monthly payments of principal and interest, each in such equal amount required to fully amortize the principal amount outstanding on the note on the last day of the deferral period by the maturity date (twenty-four months from the date of the note, or April 9, 2022).

3. On the maturity date, the Company shall pay the Lender any and all unpaid principal plus accrued and unpaid interest plus interest accrued during the deferral period.

4. If any payment is due on a date for which there is no numerical equivalent in a particular calendar month then it shall be due on the last day of such month. If any payment is due on a day that is not a business day, the payment will be made on the next business day. The term "business day" means a day other than a Saturday, Sunday or any other day on which national banking associations are authorized to be closed.

5. Payments shall be allocated among principal and interest at the discretion of Lender unless otherwise agreed or required by applicable law. Notwithstanding, in the event the Loan, or any portion thereof, is forgiven pursuant to the Paycheck Protection Program under the federal CARES Act, the amount so forgiven shall be applied to principal.

6. The Company may prepay this note at any time without payment of any premium.

The Lender is participating in the Paycheck Protection Program to help businesses impacted by the economic impact from COVID-19. Forgiveness of this loan is only available for principal that is used for the limited purposes that qualify for forgiveness under the Small Business Administration's (the "SBA") requirements, and that to obtain forgiveness, the Company must request it and must provide documentation in accordance with Small Business Administration (the "SBA") requirements, and certify that the amounts the Company is requesting to be forgiven qualify under those requirements. Forgiveness of the loan is dependent upon approval of the SBA and while the Company expects forgiveness of this Loan under the current terms of requirement by the SBA, there can be no assurance or certainty that forgiveness will in fact occur.

At June 30, 2020, the Company owes the Lender $600,000, of which $261,000 is payable in 2021 and $339,000 is payable in 2022.

13. Finance Lease Obligation

As discussed above, iBio CDMO is leasing its facility in Bryan, Texas as well as certain equipment from the Second Eastern Affiliate under the 34-year Sublease. iBio CDMO began operations at the facility on December 22, 2015 pursuant to agreements between iBio CDMO and the Second Eastern Affiliate granting iBio CDMO temporary rights to access the facility. These temporary agreements were superseded by the Sublease Agreement, dated January 13, 2016, between iBio CDMO and the Second Eastern Affiliate. The 34-year term of the Sublease expires in 2050 but may be extended by iBio CDMO for a ten-year period, so long as iBio CDMO is not in default under the Sublease. Under the Sublease, iBio CDMO is required to pay base rent at an annual rate of $2,100,000, paid in equal quarterly installments on the first day of each February, May, August and November. The base rent is subject to increase annually in accordance with increases in the Consumer Price Index ("CPI"). The base rent under the Second Eastern Affiliate's ground lease for the property is subject to adjustment, based on an appraisal of the property, in 2030 and upon any extension of the ground lease. The base rent under the Sublease will be increased by any increase in the base rent under the ground lease as a result of such adjustments. iBio CDMO is also responsible for all costs and expenses in connection with the ownership, management, operation, replacement, maintenance and repair of the property under the Sublease. The Company incurred rent expense of $150,000 and $129,000 in 2020 and 2019, respectively, related to the increase in the CPI.

In addition to the base rent, iBio CDMO is required to pay, for each calendar year during the term, a portion of the total gross sales for products manufactured or processed at the facility, equal to 7% of the first $5,000,000 of gross sales, 6% of gross sales between $5,000,001 and $25,000,000, 5% of gross sales between $25,000,001 and $50,000,000, 4% of gross sales between $50,000,001 and $100,000,000, and 3% of gross sales between $100,000,001 and $500,000,000. However, if for any calendar year period from January 1, 2018 through December 31, 2019, iBio CDMO's applicable gross sales are less than $5,000,000, or for any calendar year period from and after January 1, 2020, its applicable gross sales are less than $10,000,000, then iBio CDMO is required to pay the amount that would have been payable if it had achieved such minimum gross sales and shall pay no less than the applicable percentage for the minimum gross sales for each subsequent calendar year. As the Company adopted ASC 842 effective July 1, 2019, the minimum percentage rent is included in the finance lease obligation. Percentage rent amounted to $0 and $350,000 in 2020 and 2019, respectively.

Accrued expenses at June 30, 2020 and 2019 due the Second Eastern Affiliate amounted to $705,000 and $699,000, respectively. General and administrative expenses related to the Second Eastern Affiliate, including rent related to the increases in CPI, percentage rent discussed above and real estate taxes, were approximately $701,000 and $1,051,000 in 2020 and 2019, respectively. Interest expense related to the Second Eastern Affiliate was approximately $2,466,000 and $1,900,000 in 2020 and 2019, respectively.

The following tables present the components of lease expense and supplemental balance sheet information related to the finance lease obligation (in thousands):

	June 30, 2020
Finance Lease Cost:	
Amortization of right-of-use assets	$ 1,661
Interest on lease liabilities	2,466
Operating Lease Cost	150
Total Lease Cost	$ 4,277
Other Information	
Cash paid for amounts included in the measurement lease liabilities:	
Operating cash flows from operating lease	$ 150
Financing cash flows from finance lease obligation	$ 66

	June 30, 2020
Finance lease right-of-use assets	$ 27,616
Finance lease obligation – current portion	$ 301
Finance lease obligation – non-current portion	$ 32,007
Weighted-average remaining lease term – finance lease	**29.68 years**
Weighted-average discount rate – finance lease obligation	7.608%

Future minimum payments under the capitalized lease obligations are due as follows:

Fiscal year ending on June 30:	Principal	Interest	Total
2021	$ 301	$ 2,449	$ 2,750
2022	324	2,426	2,750
2023	350	2,400	2,750
2024	377	2,373	2,750
2025	406	2,344	2,750
Thereafter	30,550	37,513	68,063
Total minimum lease payments	32,308	$ 49,505	$ 81,813
Less: current portion	(301)		
Long-term portion of minimum lease obligations	$ 32,007		

14. Stockholders' Equity

Preferred Stock

The Company's Board of Directors is authorized to issue, at any time, without further stockholder approval, up to 1 million shares of preferred stock. The Board of Directors has the authority to fix and determine the voting rights, rights of redemption and other rights and preferences of preferred stock.

iBio CMO Preferred Tracking Stock

On February 23, 2017, the Company entered into an exchange agreement with the Eastern Affiliate pursuant to which the Company acquired substantially all of the interest in iBio CDMO held by the Eastern Affiliate and issued one share of a newly created iBio CMO Preferred Tracking Stock (the "Preferred Tracking Stock"), in exchange for 29,990,000 units of limited liability company interests of iBio CDMO held by the Eastern Affiliate at an original issue price of $13 million. After giving effect to the transaction, the Company owns 99.99% and the Eastern Affiliate owns 0.01% of iBio CDMO.

On February 23, 2017, the Board of Directors of the Company created the Preferred Tracking Stock out of the Company's 1 million authorized shares of preferred stock. Terms of the Preferred Tracking Stock include the following:

1. The Preferred Tracking Stock accrues dividends at the rate of 2% per annum on the original issue price. Accrued dividends are cumulative and are payable if and when declared by the Board of Directors, upon an exchange of the shares of Preferred Tracking Stock and upon a liquidation, winding up or deemed liquidation (such as a merger) of the Company. As of June 30, 2020, no dividends have been declared. Accrued dividends total approximately $871,000 and $610,000 at June 30, 2020 and 2019, respectively.

2. The holders of Preferred Tracking Stock, voting separately as a class, are entitled to approve by the affirmative vote of a majority of the shares of Preferred Tracking Stock outstanding any amendment, alteration or repeal of any of the provisions of, or any other change to, the Certificate of Incorporation of the Company or the Certificate of Designation that adversely affects the rights, powers or privileges of the Preferred Tracking Stock, any increase in the number of authorized shares of Preferred Tracking Stock, the issuance or sale of any additional shares of Preferred Tracking Stock or any securities convertible into or exercisable or exchangeable for Preferred Tracking Stock, the creation or issuance of any shares of any additional class or series of capital stock unless the same ranks junior to the Preferred Tracking Stock, or the reclassification or alteration of any existing security of the Company that is junior to or *pari passu* with the Preferred Tracking Stock, if such reclassification or alteration would render such other security senior to the Preferred Tracking Stock.

3. Except as required by applicable law, the holders of Preferred Tracking Stock have no other voting rights.

4. No dividend may be declared or paid or set aside for payment or other distribution declared or made upon the Company's common stock and no common stock may be redeemed, purchased or otherwise acquired for any consideration by the Company unless all accrued dividends on all outstanding shares of Preferred Tracking Stock are paid in full.

At any time, at our election or the election of the Eastern Affiliate, the outstanding share of iBio CMO Preferred Tracking Stock may be exchanged for 29,990,000 units of limited liability company interests of iBio CDMO. Following such exchange, we would own a 70% interest in iBio CDMO and the Eastern Affiliate would own a 30% interest.

Series A Convertible Preferred Stock ("Series A Preferred")

On June 20, 2018, the Board of Directors of the Company created the Series A Preferred, par value $0.001 per share, out of the Company's 1 million authorized shares of preferred stock. Terms of the Series A Preferred include the following:

1. Each share of Series A Preferred is convertible into an amount of shares of common stock determined by dividing the stated value of $1,000 by the conversion price in effect at such time. The original conversion price of $0.90 was adjusted to $0.20 upon the closing of the Company's public offering on October 29, 2019. See the sections below entitled *"Public Offering – June 26, 2018"* and *"Public Offering – October 29, 2019"* for further information. The number of shares of common stock to be received is limited by the beneficial ownership limitation as defined in the certificate of designation. Subject to limited exceptions, a holder of Series A Preferred would not have the right to exercise any portion of its Series A Preferred if such holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise; provided, however, that upon 61 days' prior notice to us, such holder may increase the such limitation, provided that in no event will the limitation exceed 9.99%.

2. Holders are entitled to dividends on shares of Series A Preferred equal (on an as-if-converted-to-common stock basis, without regards to conversion limitations) to and in the same form as dividends actually paid on shares of the common stock, when, as and if such dividends are paid on shares of common stock. No other dividends were declared for Series A Preferred.

3. Holders have no voting rights except as defined in the certificate of designation.

4. If at any time the Company granted, issued or sold any common stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to the holders of any class of common stock, then the holder(s) of Series A Preferred will be entitled to acquire, upon the terms applicable to such purchase rights, the aggregate purchase rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon the complete conversion of such holder's Series A Preferred (as defined).

5. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders were entitled to receive the same amount that a holder of common stock would receive if the Series A Preferred were fully converted (disregarding for such purposes any conversion limitations hereunder) into common stock at the conversion price in effect at such time. Such amounts were required be paid *pari passu* with all holders of common stock, the Series B Convertible Preferred and the Series C Convertible Preferred.

6. The Company was to reserve and keep available out of its authorized and unissued shares of common stock, for the sole purpose of issuance upon the conversion of the Series A Preferred, not less than such aggregate number of shares of the common stock as were issuable upon the conversion of the then outstanding shares of the Series A Preferred.

On June 26, 2018, the Company issued 6,300 shares of Series A Preferred as part of a public offering. See the section below entitled*"Public Offering – June 26, 2018"* for further information. In 2019, 2,223 shares of Series A Preferred were converted into 2,470,000 shares of common stock. At June 30, 2019, there were 3,987 shares of Series A Preferred outstanding. In 2020, the remaining shares of Series A Preferred were converted into 5,887,997 shares of common stock. At June 30, 2020, there were no shares of Series A Preferred outstanding.

Series B Convertible Preferred Stock ("Series B Preferred")

On June 20, 2018, the Board of Directors of the Company created the Series B Preferred, par value $0.001 per share, out of the Company's 1 million authorized shares of preferred stock. Terms of the Series B Preferred include the following:

1. Each share of Series B Preferred is convertible into an amount of shares of common stock determined by dividing the stated value of $1,000 by the conversion price in effect at such time. The original conversion price of $0.90 was adjusted to $0.20 upon the closing of the Company's public offering on October 29, 2019. See the sections below entitled *"Public Offering – June 26, 2018"* and *"Public Offering – October 29, 2019"* for further information. The number of shares of common stock to be received is limited by the beneficial ownership limitation as defined in the certificate of designation. Subject to limited exceptions, a holder of Series B Preferred will not have the right to exercise any portion of its Series B Preferred if such holder, together with its affiliates, would beneficially own over 48% of the number of shares of common stock outstanding immediately after giving effect to such exercise.

2. Holders are entitled to dividends on shares of Series B Preferred equal (on an as-if-converted-to-common stock basis, without regards to conversion limitations) to and in the same form as dividends actually paid on shares of the common stock, when, as and if such dividends are paid on shares of common stock. No other dividends shall be paid or accrued on the shares of Series B Preferred.

3. Holders have no voting rights except as defined in the certificate of designation.

4. If at any time the Company grants, issues or sells any common stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to the holders of any class of common stock, then then holder(s) of Series B Preferred will be entitled to acquire, upon the terms applicable to such purchase rights, the aggregate purchase rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon the complete conversion of such holder's Series B Preferred (as defined).

5. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders shall be entitled to receive the same amount that a holder of common stock would receive if the Series B Preferred were fully converted (disregarding for such purposes any conversion limitations hereunder) into common stock at the conversion price in effect at such time. Such amounts shall be paid *pari passu* with all holders of common stock and the Series A Convertible Preferred and the Series C Convertible Preferred.

6. The Company is required that it will at all times, reserve and keep available out of its authorized and unissued shares of common stock, for the sole purpose of issuance upon the conversion of the Series B Preferred, not less than such aggregate number of shares of the common stock as shall be issuable upon the conversion of the then outstanding shares of the Series B Preferred.

On June 26, 2018, the Company issued 5,785 shares of Series B Preferred as part of a public offering. See the section below entitled*"Public Offering – June 26, 2018"* for further information. At both June 30, 2020 and 2019, there were 5,785 shares of Series B Preferred outstanding. In August 2020, all of the shares of Series B Preferred were converted into 28,925,000 shares of common stock.

Series C Convertible Preferred Stock ("Series C Preferred")

On October 28, 2019, the Board of Directors of the Company created the Series C Preferred, par value $0.001 per share, out of the Company's 1 million authorized shares of preferred stock. Terms of the Series C Preferred included the following:

1. Each share of Series C Preferred was convertible into an amount of shares of common stock determined by dividing the stated value of $1,000 by the conversion price of $0.20, subject to adjustment. The number of shares of common stock to be received was limited by the beneficial ownership limitation as defined in the certificate of designation. Subject to limited exceptions, a holder of Series C Preferred would not have the right to exercise any portion of its Series C Preferred if such holder, together with its affiliates, would beneficially own over 4.99% (or, upon election by a holder prior to the issuance of any Series C Preferred Shares, 9.99%) of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise; provided, however, that upon prior notice to us, such holder may increase such limitation, provided that in no event will the limitation exceed 9.99% and any such increase would not be effective until the 61st day after such notice was delivered to the Company.

2. Holders were entitled to dividends on shares of Series C Preferred equal (on an as-if-converted-to-common stock basis, without regards to conversion limitations) to and in the same form as dividends actually paid on shares of the common stock, when, as and if such dividends were paid on shares of common stock. No dividends were declared for Series C Preferred.

3. Holders had no voting rights except as defined in the certificate of designation.

4. If at any time the Company granted, issued or sold any common stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to the holders of any class of common stock, then the holder(s) of Series C Preferred would be entitled to acquire, upon the terms applicable to such purchase rights, the aggregate purchase rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon the complete conversion of such holder's Series C Preferred (as defined).

5. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders were entitled to receive the same amount that a holder of common stock would receive if the Series C Preferred were fully converted (disregarding for such purposes any conversion limitations hereunder) into common stock at the conversion price in effect at such time. Such amounts were required to be paid *pari passu* with all holders of common stock, the Series A Preferred and the Series B Preferred.

6. The Company was required to reserve and keep available out of its authorized and unissued shares of common stock, for the sole purpose of issuance upon the conversion of the Series C Preferred, not less than such aggregate number of shares of the common stock as were issuable upon the conversion of the then outstanding shares of the Series C Preferred.

On October 29, 2019, the Company issued 4,510 shares of Series C Preferred as part of a public offering. See the section below entitled*"Public Offering – October 29, 2019"* for further information. From October 29, 2019 through June 30, 2020, all of the shares of Series C Preferred were converted into 22,550,000 shares of the Company's common stock. At June 30, 2020, there were no shares of Series C Preferred outstanding.

Common Stock

The number of authorized shares of the Company's common stock is 275 million. In addition, as of the filing date of this report, the Company had reserved shares of common stock for the following: (i) up to 3.517 million shares of common stock for incentive compensation (stock options and restricted stock units); and (ii) 28.925 million shares for the conversion of the Series B Preferred at the adjusted conversion rate of $0.20 per share.

Recent issuances of common stock include the following:

Public Offering – June 26, 2018

On June 26, 2018, the Company completed a public offering of 4,350,000 shares of its common stock, 6,300 shares of Series A Preferred and 5,785 shares of Series B Preferred. The public offering price per share for each of the foregoing securities was as follows: (i) $0.90 per share of common stock; (ii) $1,000 per Series A Preferred share; and (iii) $1,000 per Series B Preferred share. This public offering raised gross proceeds of $16.0 million. The shares of common stock and preferred stock were issued pursuant to an underwriting agreement entered into between the Company and A.G.P./Alliance Global Partners ("Alliance"). The Company incurred underwriting discounts, commissions and other offering expenses of approximately $854,000 related to closing and completion of this public offering.

Pursuant to the Underwriting Agreement, subject to certain exceptions, (i) the Company agreed not to sell or otherwise dispose of any shares of common stock for a period ending ninety (90) days after the date of the Underwriting Agreement and (ii) the Company's officers, directors and certain key shareholders agreed not to sell or otherwise dispose of any of Common Stock held by each of them for a period ending ninety (90) days after the date of the Underwriting Agreement, in each case, without first obtaining the written consent of the Underwriter.

The Company granted a forty-five (45)-day option to Alliance to purchase up to 2,666,666 additional shares (the "Option Shares") of common stock. On July 12, 2018, 1,500,000 shares of common stock were sold to Alliance in connection with Alliance partially exercising its over-allotment option at the public offering price of $0.90 per share. The Company received gross proceeds of $1,350,000 before deducting $159,000 of underwriting discounts, commissions and other offering expenses payable by the Company.

Public Offering – October 29, 2019

On October 29, 2019, the Company closed on an underwritten public offering with total gross proceeds of $5.0 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company. The securities offered by the Company consisted of (i) 2,450,000 shares (the "Shares") of the Company's Common Stock, (ii) 4,510 shares of the Company's newly designated Series C Preferred, (iii) 25,000,000 Series A Common Stock Purchase Warrants ("Series A Warrants") to purchase shares of the Company's Common Stock and (iv) 25,000,000 Series B Common Stock Purchase Warrants ("Series B Warrants") to purchase shares of the Company's Common Stock.

Each share of common stock was sold together with two warrants, one Series A Warrant with an expiry date on the second anniversary of the original issuance date to purchase one share of Common Stock and one Series B Warrant with an expiry date on the seventh anniversary of the original issuance date, to purchase one share of Common Stock. In addition, each of Series C Preferred Share was sold together with Series A Warrants to purchase one share of Common Stock for each share of Common Stock issuable upon conversion of the Series C Preferred Share and Series B Warrants to purchase one share of Common Stock for each share of Common Stock issuable upon conversion of the Series C Preferred Share. Each share of common stock and accompanying Warrants was sold at a combined public offering price of $0.20 and each Series C Preferred Share and accompanying Warrants was sold at a combined public offering price of $1,000.

The Shares, Series C Preferred Shares and Warrants were issued pursuant to an underwriting agreement, dated October 25, 2019. The net proceeds to the Company from the sale of the Shares, Series C Preferred Shares, and Warrants was approximately $4.52 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Due to the terms of the June 26, 2018 underwritten public offering, any remaining outstanding Series A Preferred and Series B Preferred were amended to convert at the same rate of the Series C Preferred ($0.20 per share). As a result of the reduction of the conversion rates of Series A Preferred and Series B Preferred, the Company recognized deemed dividends totaling $21,560,000.

Lincoln Park March 2020 Purchase Agreement

On March 19, 2020, the Company entered into the Lincoln Park March 2020 Purchase Agreement with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park up to an aggregate of $50,000,000 in shares of the Company's common stock over the 36-month term of the Lincoln Park March 2020 Purchase Agreement, subject to certain limitations and conditions set forth in the Lincoln Park March 2020 Purchase Agreement.

Concurrently with the execution of the Lincoln Park March 2020 Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park pursuant to which the Company agreed, among other things, to file a prospectus supplement pursuant to Rule 424(b) to register for sale under the Securities Act of 1933, as amended, the shares of common stock that may be issued and sold to Lincoln Park from time to time under the Lincoln Park March 2020 Purchase Agreement. The offer and sale of shares of Common Stock under the Lincoln Park March 2020 Purchase Agreement was made under the Company's previously filed and currently effective Registration Statement on Form S-3 which was declared effective on March 19, 2020. The prospectus supplement was filed on March 20, 2020.

The Lincoln Park March 2020 Purchase Agreement provides that, from time to time on any trading day the Company selects, the Company has the right, in its sole discretion, subject to the conditions and limitations in the Lincoln Park March 2020 Purchase Agreement, to direct Lincoln Park to purchase up to 1,000,000 shares of Common Stock (each such purchase, a "Regular Purchase") over the 36-month term of the Purchase Agreement. The purchase price of shares of Common Stock pursuant to the Lincoln Park March 2020 Purchase Agreement will be based on the prevailing market price at the time of sale as set forth in the Lincoln Park March 2020 Purchase Agreement. There are no trading volume requirements or restrictions under the Lincoln Park March 2020 Purchase Agreement. Lincoln Park's obligation under each Regular Purchase shall not exceed $5,000,000. There is no upper limit on the price per share that Lincoln Park must pay for Common Stock under the Lincoln Park March 2020 Purchase Agreement, but in no event will shares be sold to Lincoln Park on a day the Company's closing price is less than the floor price of $0.20, which shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such reorganization, recapitalization, non-cash dividend, stock split or other similar transaction, the Floor Price (the "Floor Price") shall mean the lower of (i) the adjusted price and (ii) $0.20.

Both the amount and frequency of the Regular Purchases can be increased upon the mutual agreement of the Company and Lincoln Park. The Company will control the timing and amount of any sales of shares of Common Stock to Lincoln Park.

The Company may, in its sole discretion, direct Lincoln Park to purchase additional amounts as accelerated purchases or additional accelerated purchases if on the date of a Regular Purchase the closing sale price of the Common Stock is not below the Floor Price as set forth in the Lincoln Park March 2020 Purchase Agreement. The Company and Lincoln Park may mutually agree to increase the amount of Common Stock sold to Lincoln Park on any accelerated purchase date or additional accelerated purchase date.

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Lincoln Park March 2020 Purchase Agreement or Registration Rights Agreement other than a prohibition on entering into any "Variable Rate Transaction," as defined in the Lincoln Park March 2020 Purchase Agreement.

Under applicable rules of the NYSE American, in no event may the Company issue or sell to Lincoln Park under the Lincoln Park March 2020 Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Lincoln Park March 2020 Purchase Agreement (the "Exchange Cap"), (i) unless stockholder approval is obtained to issue more than the Exchange Cap or (ii) except to the extent the issuances and sales of Common Stock pursuant to the Lincoln Park March 2020 Purchase Agreement are deemed to be at a price equal to or in excess of the greater of book or market value of the Common Stock as calculated in accordance with the applicable rules of the NYSE American.

The Lincoln Park March 2020 Purchase Agreement also prohibits the Company from directing Lincoln Park to purchase any shares of Common Stock if those shares, when aggregated with all other shares of Common Stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of the Common Stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.

The offering of Common Stock pursuant to the Lincoln Park March 2020 Purchase Agreement will terminate on the date that all shares offered by the Lincoln Park March 2020 Purchase Agreement have been sold or, if earlier, the expiration or termination of the Lincoln Park 2020 Purchase Agreement.

The net proceeds under the Lincoln Park March 2020 Purchase Agreement to us will depend on the frequency and prices at which we sell shares of common stock to Lincoln Park. Actual sales of shares of Common Stock to Lincoln Park under the Lincoln Park March 2020 Purchase Agreement and the amount of such net proceeds will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Common Stock and determinations by the Company as to other available and appropriate sources of funding for the Company. The Company intends to use the net proceeds of sales under the Lincoln Park March 2020 Purchase Agreement for working capital and general corporate purposes. As consideration for Lincoln Park's commitments under the Lincoln Park March 2020 Purchase Agreement, we issued to Lincoln Park 815,827 shares of common stock.

From March 19, 2020 to June 30, 2020, Lincoln Park was issued 16,800,000 shares of common stock for proceeds totaling approximately$18.4 million. For the period from July 1, 2020 to July 27, 2020, Lincoln Park was issued 2.67 million shares of common stock for proceeds totaling $6.79 million. No further sales of shares of our common stock will be made since we terminated the Lincoln Park March 2020 Purchase Agreement effective July 27, 2020. The Company terminated the Lincoln Park March 2020 Purchase Agreement on July 24, 2020, without fee, penalty or cost effective July 27, 2020.

Lincoln Park May 2020 Purchase Agreement

On May 13, 2020, the Company entered into the Lincoln Park May 2020 Purchase Agreement, pursuant to which the Company agreed to sell to Lincoln Park and Lincoln Park agreed to purchase 1,000,000 shares of the Company's common stock at a price of $1.09 per share for an aggregate purchase price of $1,090,000, pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-236735), filed with the Securities and Exchange Commission ("SEC") in accordance with the provisions of the Securities Act of 1933, as amended, and declared effective on March 19, 2020, and the prospectus supplement thereto dated May 14, 2020.

Equity Distribution Agreement

On June 17, 2020, as amended on July 29, 2020, the Company entered into an equity distribution agreement with UBS as sales agent pursuant to which the Company may sell from time to time shares of its common stock through UBS, for the sale of up to $72,000,000 of shares of the Company's common stock. Sales of shares of common stock made pursuant to the agreement will be made pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-236735) filed with the SEC in accordance with the provisions of the Securities Act of 1933, as amended, and declared effective on March 19, 2020, and the prospectus supplement thereto dated May 14, 2020.

Sales of the shares, if any, will be made by means of ordinary brokers' transactions at prevailing market prices at the time of sale, or as otherwise agreed with UBS. UBS will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

The Company is not obligated to make any sales of common stock under this agreement and the Company cannot provide any assurances that it will issue any shares pursuant to this agreement. The Company currently intends to use the net proceeds of this offering for operating costs, including working capital and other general corporate purposes.

The Company will pay a commission rate of up to 3.0% of the gross sales price per share sold and has agreed to reimburse UBS for the reasonable fees and disbursements of its counsel, in connection with entering into this agreement, in an amount not to exceed $50,000, in addition to certain ongoing fees and disbursements of its counsel. The agreement contains customary representations, warranties and agreements and other obligations of the parties and termination provisions. The Company has also agreed pursuant to the agreement to provide UBS with customary indemnification and contribution rights.

From June 17, 2020 to June 30, 2020, approximately 17.4 million shares of common stock were issued for gross proceeds totaling approximately $37.8 million. The Company incurred costs of approximately $1.27 million. In addition, the Company sold 2.4 million shares of common stock for net proceeds of approximately $5.55 million at the end of June 2020. The settlement dates of these sales were on July 1, 2020 and July 2, 2020. As such, the Company recorded a subscription receivable for such amount. The proceeds from the subscription receivable were collected on July 1, 2020 and July 2, 2020. For the period from July 1, 2020 to the date of the filing of this report, approximately 8.6 million shares of common stock were issued for net proceeds totaling approximately $24.6 million.

Eastern – Share Purchase Agreements

On January 13, 2016, the Company entered into a share purchase agreement with Eastern pursuant to which Eastern purchased 350,000 shares of the Company's common stock and the Company received proceeds of $2,177,000. In addition, Eastern exercised warrants it had previously acquired to purchase 178,400 shares of the Company's common stock. The Company received proceeds of approximately $945,000 from the exercise of the warrants.

On January 13, 2016, the Company entered into a separate share purchase agreement with Eastern pursuant to which Eastern agreed to purchase 650,000 shares of the Company's common stock at a price of $6.22 per share, subject to the approval of the Company's stockholders. The Company's stockholders approved the issuance of the 650,000 shares to Eastern at the Company's annual meeting on April 7, 2016. On April 13, 2016, the Company issued the 650,000 shares and received proceeds of $4,043,000. These shares were subject to a three-year standstill agreement (the "Standstill Agreement") which restricted additional acquisitions of the Company's equity by Eastern and its controlled affiliates to limit its beneficial ownership of the Company's outstanding shares of common stock to a maximum of 38% (the "Eastern Beneficial Ownership Limitation"), absent the approval by a majority of the Company's Board of Directors.

On November 27, 2017, the Company's Board of Directors authorized the Company's Chief Executive Officer to invite Eastern to purchase shares in the November 2017 public offering with Aegis Capital Corp., provided that such purchase did not result in Eastern being the beneficial owner of more than 40% of the aggregate number of shares of the Company's outstanding common stock rather than the limit of 38% set forth in the Standstill Agreement.

On June 26, 2018, in connection with the public offering with Alliance, the Company entered into an amendment (the "Amendment") to the share purchase agreement for 650,000 shares, dated January 13, 2016 (the "Purchase Agreement"), with Eastern. Pursuant to the Purchase Agreement, Eastern was subject to the Standstill Agreement (amended to 40%) and the Eastern Beneficial Ownership Limitation therein. The Amendment increased the Eastern Beneficial Ownership Limitation to 48% and extended the restrictions under the Standstill Agreement until June 26, 2020. In accordance with the terms of the Standstill Agreement, as amended, the Company's Board of Directors duly authorized the Company's Chief Executive Officer to offer Eastern to purchase shares in the public offering with Alliance, provided that, when taken together with all other equity securities of the Company beneficially owned by Eastern and its controlled affiliates following consummation of the public offering with Alliance, Eastern and its controlled affiliates would not beneficially own more than 48% of the aggregate number of shares of common stock outstanding as of the closing of the public offering with Alliance, including all shares of common stock issuable upon conversion of all outstanding shares of Series A Preferred and Series B Preferred, and provided, further, that Eastern agreed to extend the standstill restrictions for two (2) additional years beginning with the date of Eastern's or its controlled affiliate's purchase of securities in the public offering with Alliance. The restrictions under the Standstill Agreement were not extended beyond June 26, 2020.

On February 23, 2017, the Company entered into an exchange agreement with the Eastern Affiliate pursuant to which the Company acquired substantially all of the interest in iBio CDMO held by the Eastern Affiliate and issued one share of a newly created iBio CMO Preferred Tracking Stock, in exchange for 29,990,000 units of limited liability company interests of iBio CDMO held by the Eastern Affiliate at an original issue price of $13 million. After giving effect to the transactions contemplated in the Exchange Agreement, the Company owns 99.99% of iBio CDMO and the Eastern Affiliate owns 0.01% of iBio CDMO. At any time, at the Company's election or the election of the Eastern Affiliate, the outstanding share of iBio CMO Preferred Tracking Stock may be exchanged for 29,990,000 units of limited liability company interests of iBio CDMO. Following such exchange, the Company would own a 70% interest in iBio CDMO and the Eastern Affiliate would own a 30% interest.

Working Capital Contributions

In May 2018 and November 2018, the Eastern Affiliate contributed $1.093 million and $2.459 million, respectively, to iBio for working capital purposes which has been recorded as additional paid-in capital.

Warrants

As discussed above, the Company issued 25,000,000 Series A Warrants and 25,000,000 Series B Warrants as part of its October 29, 2019 public offering. The Series A Warrants were exercisable at $0.22 per share, had a term of two years and were set to expire on October 29, 2021. The Series B Warrants were exercisable at $0.22 per share, had a term of seven years and were set to expire on October 29, 2026.

On February 20, 2020, the Company entered into a warrant amendment and exchange agreement (the "Exchange Agreement") with certain holders (the "Holders") of the Company's Series A Warrants (the "Original Series A Warrants") and Series B Warrants (the "Original Series B Warrants").

Pursuant to the Exchange Agreement, the Holders agreed to exchange their Series A Warrants and Series B Warrants for (i) an aggregate of 14,999,998 shares of newly-issued Common Stock and (ii) promissory notes in the aggregate principal amount of $3,300,000 (see Note 11 – Notes Payable – Warrant Exchange). The Holders further agreed to amendments to the remaining, unexchanged Series A Warrants and Series B Warrants as described below (as amended, the "New Series A Warrants" and "New Series B Warrants," respectively, and collectively, the "New Warrants", and together with the Original Series A Warrants and Original Series B Warrants, the "Warrants"). Following the Exchange Agreement, there were an aggregate of New Warrants to purchase 9,595,002 shares of Common Stock.

Based on the terms of the Exchange Agreement, the Company recognized deemed dividends on common stock totaling $6,600,000.

From the date of the October 29, 2019 public offering through June 30, 2020, the Company issued 29.1 million shares of common stock for the exercise of various Warrants and received proceeds of $6.4 million. In addition, the Company issued 5.9 million shares of common stock for the cashless exercise of Warrants in which the "assumed proceeds" totaling $1.3 million were used to reduce the Company's balances owed for the notes described under "Note 11 - Notes Payable – Warrant Exchange". Costs related to the Warrant Exchange totaled approximately $313,000 and were offset against additional paid-in capital.

As of June 30, 2020, there were no Warrants outstanding.

15. Earnings (Loss) Per Common Share

Basic earnings (loss) per common share is computed by dividing the net income (loss) allocated to common stockholders by the weighted-average number of shares of common stock outstanding during the period. For purposes of calculating diluted earnings per common share, the denominator includes both the weighted-average number of shares of common stock outstanding during the period and the number of common stock equivalents if the inclusion of such common stock equivalents is dilutive. Dilutive common stock equivalents potentially include stock options and warrants using the treasury stock method. The following table summarizes the components of the earnings (loss) per common share calculation (in thousands, except per share amounts):

	Years ended June 30,	
	2020	**2019**
Basic and diluted numerator:		
Net loss attributable to iBio, Inc. stockholders	**$ (16,439)**	$ (17,593)
Deemed dividends – down round of Series A Preferred and Series B Preferred	**(21,560)**	-
Preferred stock dividends – iBio CMO Preferred Tracking Stock	**(261)**	(260)
Net loss available to iBio, Inc. stockholders	**$ (38,260)**	$ (17,853)
Basic and diluted denominator:		
Weighted-average common shares outstanding	**62,795**	18,926
Per share amount	**$ (0.61)**	$ (0.94)

In 2020 and 2019, the Company incurred net losses which cannot be diluted; therefore, basic and diluted loss per common share is the same. As of June 30, 2020, and 2019, shares issuable which could potentially dilute future earnings included were as follows.

	Year Ended June 30,	
	2020	**2019**
	(in thousands)	
Stock options	**3,476**	1,347
Series A Preferred	**-**	4,430
Series B Preferred	**28,925**	6,428
Restricted stock units	**41**	-
Shares excluded from the calculation of diluted loss per share	**32,442**	12,205

16. Share-Based Compensation

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Operations (in thousands):

	Year Ended June 30,	
	2020	**2019**
Research and development	**$ 55**	$ 26
General and administrative	**333**	215
Totals	**$ 388**	$ 241

Stock Options

2008 Omnibus Equity Incentive Plan (the "2008 Plan")

On August 12, 2008, the Company adopted the iBioPharma 2008 Omnibus Equity Incentive Plan for employees, officers, directors and external service providers. The 2008 Plan provided that the Company may grant options to purchase stock and/or make awards of restricted stock. Stock options granted under the 2008 Plan may be either incentive stock options (as defined by Section 422 of the Internal Revenue Code of 1986, as amended) or non-qualified stock options at the discretion of the Board of Directors. Vesting of service awards occurred ratably on the anniversary of the grant date over the service period, generally three or five years, as determined at the time of grant. Vesting of performance awards occurred when the performance criteria had been satisfied. The Company used historical data to estimate forfeiture rates. The 2008 Plan had a term of ten (10) years and, as a result, the 2008 Plan expired by its terms on August 12, 2018.

iBio, Inc. 2018 Omnibus Equity Incentive Plan (the "2018 Plan")

On December 18, 2018, the Company's stockholders, upon recommendation of the Board of Directors on November 9, 2018, approved the 2018 Plan. On March 5, 2020 at the Company's 2019 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares of common stock authorized for issuance thereunder from 3.5 million shares to 6.5 million shares and to incorporate changes to include restricted stock units and performance-based awards as grant types issuable under the 2018 Plan. The total number of shares of common stock reserved under the 2018 Plan is 6.5 million. Stock options granted under the 2018 Plan may be either incentive stock options (as defined by Section 422 of the Internal Revenue Code of 1986, as amended), non-qualified stock options, or restricted stock and determined at the discretion of the Board of Directors.

Vesting of service awards will be determined by the Board of Directors and stated in the award agreements. In general, vesting will occur ratably on the anniversary of the grant date over the service period, generally three or five years, as determined at the time of grant. Vesting of performance awards will occur when the performance criteria has been satisfied. The Company uses historical data to estimate forfeiture rates. The 2018 Plan has a term of ten (10) years and expires by its terms on November 9, 2028.

In addition, on December 18, 2018, the Company's stockholders, upon recommendation of the Board of Directors, also approved an amendment to the Company's 2008 Plan to allow the Company to permit a one-time option exchange program under which the Company would offer eligible employees and non-employee directors the opportunity to exchange certain outstanding options on a four-for-three basis for new stock options exercisable at a lower price under the 2018 Plan (the "Option Exchange").

On January 22, 2019, the Company filed with the Securities and Exchange Commission a Tender Offer Statement on Schedule TO defining the terms and conditions of the Option Exchange, whereby the Company was offering eligible employees and non-employee directors ("Eligible Option Holders") the opportunity to exchange for new options covering a lesser number of shares of the Company's common stock ("Replacement Options"), at a ratio of four-for-three (the "Exchange Ratio"), any options issued by the Company prior to January 22, 2019 that were outstanding under its 2008 Plan that had an exercise price greater than the closing price per share of iBio's common stock on the NYSE American on the grant date of the Replacement Options ("Eligible Exchange Options"), so that for each four shares of common stock subject to an Eligible Exchange Option, the option holder would receive a Replacement Option to purchase three shares under the 2018 Plan. On February 20, 2019, the completion date of the Option Exchange (the "Replacement Option Grant Date"), the Company canceled the options accepted for exchange and granted 874,310 Replacement Options in exchange for 1,165,750 options issued under the 2008 Plan.

The Replacement Options:

- have a per-share exercise price of $0.93, which was equal to the closing price per share of the Company's common stock on the Replacement Option Grant Date;
- have a five-year term beginning on February 20, 2019 and vest one year later on February 20, 2020. Generally, the Underwater Options had been scheduled to vest over four years following the recipient's employment start date or the date of grant. As of November 19, 2018, approximately 94% of the shares covered by the Underwater Options already were vested. All other terms and conditions of the new stock options are generally be consistent with the terms and conditions of iBio's standard time-vesting stock option grants;
- are of the same type of options as the surrendered options. Eligible Option Holders holding nonqualified stock options received Replacement Options in the form of nonqualified stock options and Eligible Option Holders holding incentive stock options received Replacement Options in the form of incentive stock options; and
- have the terms and be subject to the conditions as provided for in the 2018 Plan and option award agreement.

Issuances of stock options during 2020 were as follows:

- In March 2020, the Company issued options to acquire 908,300 shares of common stock to various members of management and employees. The exercise price is $1.15 per share. The options vest over a four-year period and expire in ten years;
- On April 21, 2020, the Company issued to Thomas Isett ("Isett"), the Company's Chief Executive Officer (effective March 2020) and Chairman of the Company, options to acquire 975,000 shares of the Company's common stock at an exercise price of $0.8953 per share. The options vest over a three-year period and expire in ten years;
- On June 1, 2020, the Company issued options to acquire 100,000 shares of common stock to a member of management. The exercise price is $1.66 per share. The options vest over a four-year period and expire in ten years; and
- On June 20, 2020, the Company issued to Robert Kay, the Company's former Chief Executive Officer (resigned March 2020), options to acquire 400,000 shares of the Company's common stock at an exercise price of $1.47 per share. The options vest monthly over a two-year period and expire in ten years.

Issuances of stock options during 2019 were as follows:

Effective April 1, 2019, the Company granted each member of its Board of Directors a stock option agreement under the 2018 Plan whereby each director has the option to purchase 50,000 shares of the Company's common stock at a price of $0.90 per share. The options vest over a period of three years and expire in ten years.

The following table summarizes all stock option activity during the years ended June 30, 2020 and 2019:

	Stock Options	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of July 1, 2018	1,364,583	$ 12.01	4.9	$ -
Granted	400,000	$ 0.90		
Issued under Option Exchange	874,310	$ 0.93		
Forfeited/expired/exchanged	(1,292,374)	$ 12.08		
Outstanding as of June 30, 2019	1,346,519	$ 1.45	6.1	$ -
Granted	2,383,300	$ 1.11		
Exercised	(139,392)	$ 0.93		
Forfeited/expired	(114,654)	$ 3.32		
Outstanding as of June 30, 2020	3,475,773	$ 1.18	8.2	$ 4,042
As of June 30, 2020, vested and expected to vest	3,424,064	$ 1.18	8.3	$ 3,987
Exercisable as of June 30, 2020	983,442	$ 1.40	4.6	$ 1,221

The following table summarizes information about options outstanding and exercisable at June 30, 2020:

	Options Outstanding and Exercisable			
	Number Outstanding	Weighted-Average Remaining Life In Years	Weighted-Average Exercise Price	Number Exercisable
Exercise prices:				
$0.90 - $1.40	3,351,606	8.3	$ 1.03	959,442
$1.66 - $2.49	100,333	9.9	1.667	333
$2.53 - $3.80	500	7.7	2.53	333
$7.30 - $10.95	9,334	1.9	8.59	9,334
$26.90 - $40.35	14,000	0.9	27.47	14,000
	3,475,773	8.2	$ 1.18	983,442

The total fair value of stock options that vested during 2020 and 2019 was approximately $433,000 and $57,000, respectively. The total cash received for stock options that were exercised during 2020 and 2019 was approximately $130,000 and $0, respectively. The total intrinsic value of stock options that were exercised during 2020 and 2019 was approximately $102,000 and $0, respectively. As of June 30, 2020, there was approximately $2,174,000 of total unrecognized compensation cost related to non-vested stock options that the Company expects to recognize over a weighted-average period of 2.9 years.

The weighted-average grant date fair value of stock options granted during 2020 and 2019 was $0.97 and $0.43 per share, respectively. The Company estimated the fair value of options granted using the Black-Scholes option pricing model with the following assumptions:

	2020	2019
Weighted average risk-free interest rate	0.60%	2.45%
Dividend yield	0%	0%
Volatility	97.5%	97.5%
Expected term (in years)	9	9

The aggregate intrinsic value in the table above represents the total intrinsic value, based on the Company's closing stock price of $2.22 as of June 30, 2020, $0.71 as of June 30, 2019, and $0.90 as of June 30, 2018, which would have been received by the option holders had all option holders exercised their options as of that date.

Restricted Stock Units ("RSU's"):

On March 27, 2020, the Company issued RSU's to acquire 41,150 shares of common stock to various employees at a market value of $1.15 per share. The RSU's vest over a four-year period. The grant-date fair value of the RSU's totaled approximately $47,000.

As of June 30, 2020, there was approximately $41,000 of total unrecognized compensation cost related to non-vested RSU's that the Company expects to recognize over a weighted-average period of 3.7 years.

17. Related Party Transactions

Novici Biotech, LLC

In January 2012, the Company entered into an agreement with Novici in which iBio's President is a minority stockholder. See Note 9 – Significant Vendors for further details.

Agreements with Eastern Capital Limited and its Affiliates.

As more fully discussed in Note 14 – Stockholders' Equity, the Company entered into two share purchase agreements with Eastern and the Standstill Agreement.

Concurrently with the execution of the Purchase Agreements, iBio entered into a contract manufacturing joint venture with the Eastern Affiliate to develop and manufacture plant-made pharmaceuticals through iBio CDMO. The Eastern Affiliate contributed $15.0 million in cash to iBio CDMO, for a 30% interest in iBio CDMO. iBio retained a 70% equity interest in iBio CDMO. As the majority equity holder, iBio has the right to appoint a majority of the members of the Board of Managers that manages the iBio CDMO joint venture. Specified material actions by the joint venture require the consent of iBio and the Eastern Affiliate. iBio contributed to the capital of iBio CDMO a royalty bearing license, which grants iBio CDMO a non-exclusive license to use the iBio's proprietary technologies for research purposes and an exclusive U.S. license for manufacturing purposes. iBio retains all other rights in its intellectual property, including the right for itself to commercialize products based on its proprietary technologies or to grant licenses to others to do so.

In connection with the joint venture, the Second Eastern Affiliate, which controls the subject property as sublandlord, granted iBio CDMO the Sublease of a Class A life sciences building in Bryan, Texas, located on land owned by the Texas A&M system, designed and equipped for plant-made manufacture of biopharmaceuticals. The terms of the sublease are described in Note 13 – Finance Lease Obligation.

The Standstill Agreement took effect upon the issuance of the shares to Eastern pursuant to a share purchase agreement for the acquisition of 650,000 shares of common stock. The Standstill Agreement has been amended twice so that Eastern and its controlled affiliates are limited to its beneficial ownership of the Company's outstanding shares of common stock to a maximum of 48%, absent approval by a majority of the Company's Board of Directors. Eastern agreed to extend the standstill restrictions for two (2) additional years beginning with the date of Eastern's or its controlled affiliate's purchase of securities in the public offering with Alliance. See Note 14 – Stockholders' Equity for further information.

On February 23, 2017, the Company entered into an exchange agreement with the Eastern Affiliate pursuant to which the Company acquired substantially all of the interest in iBio CDMO held by the Eastern Affiliate and issued one share of the Preferred Tracking Stock in exchange for 29,990,000 units of limited liability company interests of iBio CDMO held by the Eastern Affiliate at an original issue price of $13 million. After giving effect to the transactions in the Exchange Agreement, the Company owns 99.99% of iBio CDMO and the Eastern Affiliate owns 0.01% of iBio CDMO. At any time, at the Company's election or the election of the Eastern Affiliate, the outstanding share of iBio CMO Preferred Tracking Stock may be exchanged for 29,990,000 units of limited liability company interests of iBio CDMO. Following such exchange, the Company would own a 70% interest in iBio CDMO and the Eastern Affiliate would own a 30% interest.

Director Consulting Agreement

i.e. Advising, LLC ("IEA") was retained by the Company as a strategy and management consultant pursuant to a Consulting Agreement, dated as of February 22, 2019 (the "Consulting Agreement"), with services provided pursuant to statements of work entered into between the Company and Consultant from time to time. Mr. Isett was the Managing Director and sole owner of IEA. Effective as of May 1, 2019, the Company entered into a Statement of Work (the "May 1, 2019 SOW") pursuant to the Consulting Agreement, which provided for an engagement to be conducted on a retainer basis with Mr. Isett as the primary engagement resource, at a rate of $40,000 per month, and on a time and materials basis for all other engagement resources provided by IEA, billable at the rate of $85 to $450 per hour. IEA and the Company entered into an additional Statement of Work on December 1, 2019 (the "December 1, 2019 SOW"), which provided that Consultant would be entitled to a bonus of 3% to 4.5% of the transaction value if the Company or any of its assets were sold during the term of the Statement of Work. Consultant and the Company agreed to terminate the Consulting Agreement and both the May 1, 2019 SOW and December 1, 2019 SOW on March 10, 2020, when Mr. Isett became the Company's Chief Executive Officer.

Consulting expenses totaled approximately $425,000 and $168,000 in 2020 and 2019, respectively. At June 30, 2020 and 2019, the Company owed the Consultant $0 and $60,000, respectively.

KBI Consulting

On April 1, 2020, the Company entered into a consulting agreement with KBI Consulting for business support services provided by Mr. Isett's wife. Per the consulting agreement the business support services are billed at $5,800 per month. Consulting expenses totaled approximately $17,000 in 2020. At June 30, 2020, the Company owed the Consultant $5,800.

18. Income Taxes

The components of net loss consist of the following (in thousands):

	For the Years Ended June 30,	
	2020	**2019**
United States	**$ (16,429)**	$ (17,576)
Brazil	**(15)**	(21)
Total	**$ (16,444)**	$ (17,597)

The components of the provision (benefit) for income taxes consist of the following (in thousands):

	For the Years Ended June 30,	
	2020	**2019**
Current – Federal, state and foreign	**$ -**	$ -
Deferred – Federal	**(1,560)**	(3,690)
Deferred – State	**(428)**	(990)
Deferred – Foreign	**-**	-
Total	**(1,988)**	(4,680)
Change in valuation allowance	**1,988**	4,680
Income tax expense	**$ -**	$ -

The Company has deferred income taxes due to income tax credits, net operating loss carryforwards, and the effect of temporary differences between the carrying values of certain assets and liabilities for financial reporting and income tax purposes.

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	As of June 30,	
	2020	**2019**
Deferred tax assets (liabilities):		
Net operating loss	**$ 25,179**	$ 21,427
Share-based compensation	**93**	2,236
Research and development tax credits	**1,568**	1,534
Basis in iBio CDMO	**973**	687
Intangible assets	**(173)**	(233)
Vacation accrual and other	**18**	19
Valuation allowance	**(27,658)**	(25,670)
Total	**$ -**	$ -

The Company has a valuation allowance against the full amount of its net deferred tax assets due to the uncertainty of realization of the deferred tax assets due to the operating loss history of the Company. The Company currently provides a valuation allowance against deferred taxes when it is more likely than not that some portion, or all of its deferred tax assets will not be realized. The valuation allowance could be reduced or eliminated based on future earnings and future estimates of taxable income.

Federal net operating losses of approximately $5.5 million were used by the Former Parent prior to June 30, 2008 and are not available to the Company. The Former Parent allocated the use of the Federal net operating losses available for use on its consolidated Federal tax return on a pro rata basis based on all of the available net operating losses from all the entities included in its control group.

U.S. federal net operating losses of approximately $102.3 million are available to the Company as of June 30, 2020, of which $71.3 million will expire at various dates through 2039 and $31.0 million with no expiration date. These carryforwards could be subject to certain limitations in the event there is a change in control of the Company pursuant to Internal Revenue Code Section 382, though the Company has not performed a study to determine if the loss carryforwards are subject to these Section 382 limitations. The Company has a research and development credit carryforward of approximately $1.5 million at June 30, 2020. In addition, the Company has foreign net operating losses totaling approximately $123,000 with no expiration date.

A reconciliation of the statutory tax rate to the effective tax rate is as follows:

	Years Ended June 30,	
	2020	**2019**
Statutory federal income tax rate	**21%**	21%
State (net of federal benefit)	**6%**	6%
Research and development tax credit	**-%**	1%
Cancelled and expired non-qualifying stock options	**(14)%**	-%
Change in valuation allowance	**(13)%**	(28)%
Effective income tax rate	**-%**	-%

The Company has not been audited in connection with income taxes. iBio files U.S. Federal and state income tax returns subject to varying statutes of limitations. The 2016 through 2019 tax returns generally remain open to examination by U.S. Federal authorities and by state tax authorities. In addition, the 2015 through 2019 Brazilian federal tax returns remain open to examination by Brazil's federal tax authorities.

19. Commitments and Contingencies

COVID-19

As a result of the impact of the COVID-19 pandemic crisis, the Company does not anticipate any significant threat to its operations at this point in time. Due to the general unknown nature surrounding the crisis, the Company cannot reasonably estimate the potential for any future impacts on operations or its liquidity. In recognition of the significant threat to the liquidity of the financial markets posed by COVID-19, on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), was signed into law to provide emergency assistance to qualifying businesses and individuals. There can be no assurance that these interventions by the government will be successful, and the financial markets may experience significant contractions in available liquidity. On April 16, 2020, the Company received $600,000 related to its filing under the Paycheck Protection Program and CARES Act. It is not possible at this time to estimate the further need, availability, extent or impact of any additional such relief. Although the Company does not anticipate current operational difficulties, the risk exists that further COVID-19 developments may negatively impact the Company's financial condition and restrict the availability of liquidity for its operational needs.

Agreements

Lease – Bryan, Texas
As discussed above, iBio CDMO is leasing its facility in Bryan, Texas from the Second Eastern Affiliate under the Sublease. See Note 13 – Finance Lease Obligations for more details of the Sublease.

Lawsuits

On March 17, 2015, the Company filed a Verified Complaint in the Court of Chancery of the State of Delaware against Fraunhofer and Vidadi Yusibov ("Yusibov"), Fraunhofer CMB's Executive Director, seeking monetary damages and equitable relief based on Fraunhofer's material and continuing breaches of their contracts with the Company. On September 16, 2015, the Company voluntarily dismissed its action against Yusibov, without prejudice, and thereafter on September 29, 2015, the Company filed a Verified Amended Complaint against Fraunhofer alleging material breaches of its agreements with the Company and seeking monetary damages and equitable relief against Fraunhofer. The Court bifurcated the action to first resolve the threshold question in the case – the scope of iBio's ownership of the technology developed or held by Fraunhofer – before proceeding with the rest of the case and the parties stipulated their agreement to that approach. After considering the parties' written submissions and oral argument, the Court resolved the threshold issue in favor of iBio on July 29, 2016, holding that iBio owns all proprietary rights of any kind to all plant-based technology of Fraunhofer developed or held as of December 31, 2014, including know-how, and was entitled to receive a technology transfer from Fraunhofer. Fraunhofer's motion to dismiss iBio's contract claims was denied by the Court on February 24, 2017. The Court at that time also granted, over Fraunhofer's opposition, iBio's motion to supplement and amend the Complaint to add additional state law claims against Fraunhofer. Fraunhofer filed an answer and counterclaims in March 2017, but in May 2017, Fraunhofer obtained new counsel, and with iBio's agreement (as a matter of procedure), filed an amended answer and amended counterclaims in July 2017. The Company replied to those counterclaims on August 9, 2017. In November 2017, the Company engaged new counsel to further lead its litigation efforts, and on November 3, 2017, the Company filed a separate Verified Complaint in the Court of Chancery of the State of Delaware against Fraunhofer-Gesellschaft, the European unit of Fraunhofer (the "Second Complaint"). The Second Complaint follows iBio's pending litigation filed in March 2015, described above, against Fraunhofer USA, Inc., the U.S. unit of Fraunhofer. The complaint against Fraunhofer-Gesellschaft was dismissed by the Delaware Chancery Court on December 10, 2018 as untimely filed. The dismissal of this action has no effect on the action against the U.S. unit of Fraunhofer.

The case against Fraunhofer has proceeded and fact and expert discovery has now closed.

Fraunhofer filed a motion for summary judgment in November 2019, arguing that the Company's claims should be dismissed as preempted or duplicative, and that certain claims should be time barred. Briefing was completed in January 2020, and a hearing on Fraunhofer's motion was held on June 11, 2020. On September 25, 2020, the Court granted in part and denied in part Fraunhofer's motion for summary judgment. The Court granted Fraunhofer's motion for summary judgment as to iBio's fraud, conversion, constructive trust, partial rescission, and unjust enrichment claims. The U.S. Court denied Fraunhofer's motion for summary judgment as to iBio's declaratory judgment, breach of contract, misappropriation of trade secrets, tortious interference, and deceptive trade practices claims, and ruled that those claims could proceed to trial.

On January 6, 2020, the Company filed a motion in the Court of Chancery of the State of Delaware to initiate new litigation against Fraunhofer-Gesellschaft through an amendment to its Verified Amended Complaint. The motion asserts that new evidence reveals that Fraunhofer-Gesellschaft exercised complete dominion and control over its US subsidiary to wrongfully access and direct use of iBio's intellectual property on many occasions with new and different third parties. The Court denied the Company's motion for leave to amend at a hearing on June 11, 2020, without prejudice and with leave to refile the complaint at a later date.

The case is set for trial on March 1 to 5, 2021. The Company is unable to predict the further outcome of this action at this time.

20. Employee 401(K) Plan

Commencing January 1, 2018, the Company established the iBio, Inc. 401(K) Plan (the "Plan"). Eligible employees of the Company may participate in the Plan, whereby they may elect to make elective deferral contributions pursuant to a salary deduction agreement and receive matching contributions upon meeting age and length-of-service requirements. The Company will make a 100% matching contribution that is not in excess of 5% of an eligible employee's compensation. In addition, the Company may make qualified non-elective contributions at its discretion. Employer contributions made to the Plan totaled approximately $97,000 and $126,000 in 2020 and 2019, respectively.

21. Segment Reporting

In accordance with FASB ASC 280, "*Segment Reporting*," the Company discloses financial and descriptive information about its reportable segments. The Company operates in two segments, (i) our biologics development and licensing activities, conducted within iBio, Inc. and (ii) our CDMO segment, conducted within iBio CDMO. These segments are components of the Company about which separate financial information is available and regularly evaluated by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The accounting policies of the segments are the same as those described in the Summary of Significant Accounting Policies. Please note that certain totals may not sum due to rounding.

Year Ended June 30, 2020 (in thousands)	**iBio, Inc.**	**iBio CDMO**	**Eliminations**	**Total**
Revenues - external customers	**$ 1,546**	**$ 92**	**$ -**	**$ 1,638**
Revenues - intersegment	**793**	**1,665**	**(2,458)**	**-**
Research and development	**1,106**	**3,805**	**(1,698)**	**3,213**
General and administrative	**5,381**	**7,807**	**(760)**	**12,428**
Operating loss	**(4,148)**	**(9,855)**	**-**	**(14,003)**
Interest expense	**-**	**(2,466)**	**-**	**(2,466)**
Interest and other income	**24**	**1**	**-**	**25**
Consolidated net loss	**(4,124)**	**(12,320)**	**-**	**(16,444)**
Total assets	**103,667**	**31,868**	**(41,346)**	**94,189**
Finance lease ROU assets	**-**	**27,616**		**27,616**
Fixed assets, net	**-**	**3,657**	**-**	**3,657**
Intangible assets, net	**1,144**	**-**	**-**	**1,144**
Amortization of ROU assets	**-**	**1,661**	**-**	**1,661**
Depreciation expense	**1**	**281**	**-**	**282**
Amortization of intangible assets	**298**	**-**	**-**	**298**

Year Ended June 30, 2019 (in thousands)	**iBio, Inc.**	**iBio CDMO**	**Eliminations**	**Total**
Revenues - external customers	$ 2,018	$ -	$ -	$ 2,018
Revenues - intersegment	1,465	1,995	(3,460)	-
Research and development	4,344	3,164	(2,034)	5,474
General and administrative	4,297	9,461	(1,426)	12,332
Operating loss	(5,158)	(10,630)	-	(15,788)
Interest expense	-	(1,900)	-	(1,900)
Interest and other income	79	12	-	91
Consolidated net loss	(5,079)	(12,518)	-	(17,597)
Total assets	37,442	6,399	(13,255)	30,586
Fixed assets, net	2	24,378	-	24,380
Intangible assets, net	1,374	-	-	1,374
Depreciation expense	2	1,425	-	1,427
Amortization of intangible assets	322	-	-	322

22. Notices of Delisting or Failure to Satisfy a Continued Listing Rule or Standard

On October 16, 2019, the Company received notification from the NYSE American (the "Exchange") that the Company is not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide (the "Guide"), which applies if a listed company has stockholders' equity of less than $4,000,000 and has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years, and Section 1003(a)(iii) of the Guide, which applies if a listed company has stockholders' equity of less than $6,000,000 and has reported losses from continuing operations and/or net losses in its five most recent fiscal years. On December 9, 2019, the Company received a further notice from the Exchange that the Company currently is below the Exchange's continued listing standards set forth in Section 1003(a)(i) of the Guide, which applies if a listed company has stockholders' equity of less than $2,000,000 and has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years. The December 9, 2019 notification from the Exchange also stated that the Exchange has determined that the Company's securities have been selling for a low price per share for a substantial period of time and pursuant to Section 1003(f)(v) of the Guide, the Company's continued listing on the Exchange is predicated on the Company effecting a reverse stock split or otherwise demonstrating sustained improvement in its share price within a reasonable period of time, which the Exchange has determined to be no later than June 9, 2020. The Exchange notified us on June 9, 2020, that we had regained compliance with this section of the Exchange's listing standards.

On January 10, 2020, the Company received notice from the Exchange that NYSE Regulation has accepted the Company's November 15, 2019 plan to regain compliance with the Exchange's continued listing standards set forth in Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Guide and has granted a plan period through December 9, 2020, subject to periodic review by the Exchange, including quarterly monitoring, to regain compliance with the initiatives outlined in the plan. The Exchange notified us on October 1, 2020, that we had regained compliance with all of the Exchange continued listing standards set forth in Part 10 of the Guide. Specifically, the notification stated that we had resolved the continued listing deficiency with respect to Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Guide by meeting the requirements of the $50 million market capitalization exemption in Section 1003(a) of the Guide.

The NYSE American notifications did not affect the Company's business operations or its reporting obligations under the Securities and Exchange Commission regulations and rules and did not conflict with or cause an event of default under any of the Company's material agreements.

In addition, the Company expects revenues related to its CDMO core services offering and potential commercialization of its technologies and the potential development and eventual commercialization of proprietary pipeline products. The Company cannot be certain it will succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

As of June 30, 2020, the Company's stockholders' equity balance is $56.6 million. In order to maintain its listing with NYSE American, the Company must remain in compliance with the continued listing standards as set forth in Section 1003(a)(iii) of the Company Guide, which applies if a listed company has stockholders' equity of less than $6,000,000 and has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. Based on the June 30, 2020, stockholders' equity balance, the Company is above the Exchange compliance requirement with Section 1003(a)(iii).

23. Subsequent Events

On October 1, 2020 the Company loaned $1,500,000 to SAFI BIOSOLUTIONS, INC. in exchange for a convertible note receivable. The Company also executed a PROCESS DEVELOPMENT AND CLINICAL MANUFACTURING MASTER SERVICES AGREEMENT with SAFI on the same date.

Interest will accrue on the unpaid principal balance at a rate equal to 5% per annum and is not due until the three-year anniversary of the note.

The principal amount, plus accrued interest, will be recorded as a long-term asset.

24. Disclosure of Prior Period Financial Statement Error

The Company revised previously issued condensed consolidated financial statements as of March 31, 2020 and for the three- and nine-month periods ended March 31, 2020 for an error related to the omission of a share issuance completed during the period (Note 3). A summary of revisions to our previously reported financial statements presented herein for comparative purposes is included below:

Revised Consolidated Balance Sheets

Consolidated balance sheet

	March 31,2020		
(In thousands)	As Reported	Adjustment	As Revised
Subscription receivable	$ -	$ 2,190	$ 2,190
Total current assets	10,304	2,190	12,494
Total Assets	42,220	2,190	44,410
APIC	150,774	2,190	152,964
Total equity	3,957	2,190	6,147
Total liabilities and equity	42,220	2,190	44,410

Revised Consolidated Statement of Operations

	Three Months Ended March 31, 2020		
	As Reported	Adjustment	As Revised
Loss per common share attributable to iBio, Inc. stockholders - basic and diluted	$ (0.06)	0.00	(0.06)
Weighted-average common shares outstanding - basic and diluted (000's)	79,719	290	80,009

	Nine Months Ended March 31, 2020		
Loss per common share attributable to iBio, Inc. stockholders - basic and diluted	$ (0.74)	0.00	(0.74)
Weighted-average common shares outstanding - basic and diluted (000's)	47,018	96	47,114

Exhibit 4.9

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

iBio, Inc. (the "Company," "we," "us," and "our") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is our common stock, par value $0.001 per share (the "common stock").

General

The following is a description of the material terms of our common stock. This is a summary only and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), and our First Amended and Restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to our Annual Report on Form 10-K for the fiscal year ended June 30, 2020, of which this Exhibit 4.9 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

Description of Common Stock

Authorized Shares of Common Stock. We currently have authorized 275,000,000 shares of common stock. As of October 8, 2020, we had 180,287,751 issued and outstanding shares of common stock.

Voting. The holders of our common stock are entitled to one vote per share on all matters to be voted upon by the stockholders and are not entitled to cumulative voting for the election of directors.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our Board of Directors out of legally available funds.

Liquidation. In the event of liquidation, dissolution or winding up of our company, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the preferences of preferred stockholders.

Rights and Preferences. The holders of our common stock have no preemptive, conversion or other subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that is currently outstanding or that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our issued and outstanding shares of common stock are fully paid and nonassessable.

Potential Anti-Takeover Effects

Certain provisions set forth in our Certificate of Incorporation and Bylaws and in Delaware law, which are summarized below, may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

Pursuant to our Certificate of Incorporation, our Board of Directors may issue additional shares of common or preferred stock. Any additional issuance of common stock could have the effect of impeding or discouraging the acquisition of control of us by means of a merger, tender offer, proxy contest or otherwise, including a transaction in which our stockholders would receive a premium over the market price for their shares, and thereby protect the continuity of our management. Specifically, if in the due exercise of its fiduciary obligations, the Board of Directors were to determine that a takeover proposal was not in our best interest, shares could be issued by our Board of Directors without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover by:

- Diluting the voting or other rights of the proposed acquirer or insurgent stockholder group;
- Putting a substantial voting bloc in institutional or other hands that might undertake to support the incumbent Board of Directors; or
- Effecting an acquisition that might complicate or preclude the takeover.

Our Certificate of Incorporation also allows our Board of Directors to fix the number of directors in our Bylaws. Cumulative voting in the election of directors is specifically denied in our Certificate of Incorporation. The effect of these provisions may be to delay or prevent a tender offer or takeover attempt that a stockholder may determine to be in his, her or its best interest, including attempts that might result in a premium over the market price for the shares held by the stockholders.

In addition to the foregoing, our Certificate of Incorporation and Bylaws contain the following provisions:

Staggered Board. Our Board of Directors is divided into three classes of directors, Class I, II and III, with each class serving staggered 3-year terms.

Nominations of Directors and Proposals of Business. Our Bylaws generally regulate nominations for election of directors by stockholders and proposals of business at annual meetings. In general, Sections 1.10 and 1.11 of our Bylaws requires stockholders intending to submit nominations or proposals at an annual meeting of stockholders to provide the Company with advance notice thereof, including information regarding the nomination or the stockholder proposing the business as well as information regarding the nominee or the proposed business. Sections 1.10 and 1.11 of our Bylaws provides a time period during which nominations or business must be provided to the Company that will create a predictable window for the submission of such notices, eliminating the risk that the Company finds a meeting will be contested after printing its proxy materials for an uncontested election and providing the Company with a reasonable opportunity to respond to nominations and proposals by stockholders.

Board Vacancies. Our Bylaws generally provide that only the Board of Directors (and not the stockholders) may fill vacancies and newly created directorships.

Special Meeting of Stockholders. Our Bylaws generally provide that special meetings of stockholders for any purpose or purposes for which meetings may be lawfully called, may be called at any time by our Board of Directors, the Chairman of the Board, the Chief Executive Officer or by one or more stockholders holding shares in the aggregate entitled to cast not less than fifty percent (50%) of the votes at that meeting. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

While the foregoing provisions of our Certificate of Incorporation, Bylaws and Delaware law may have an anti-takeover effect, these provisions are intended to enhance the likelihood of continuity and stability in the composition of the Board of Directors and in the policies formulated by the Board of Directors and to discourage certain types of transactions that may involve an actual or threatened change of control. In that regard, these provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our common stock that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

Delaware Takeover Statute

In general, Section 203 of the Delaware General Corporation Law prohibits a Delaware corporation that is a public company from engaging in any "business combination" (as defined below) with any "interested stockholder" (defined generally as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with such entity or person) for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 of the Delaware General Corporation Law defines "business combination" to include: (1) any merger or consolidation involving the corporation and the interested stockholder; (2) any sale, transfer, pledge or other disposition of ten percent or more of the assets of the corporation involving the interested stockholder; (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Listing of Common Stock on the NYSE American

Our common stock is currently listed on the NYSE American under the trading symbol "IBIO."

Transfer Agent

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. They are located at 1 State Street, 30th floor, New York, New York 10004. Their telephone number is (212) 509-4000.

Exhibit 21.1

Subsidiaries of Registrant

iBioDefense Biologics LLC ("iBioDefense") is wholly-owned and incorporated in Delaware

iBio Peptide Therapeutics LLC ("iBio Peptide") is wholly-owned and incorporated in Delaware

iBio Manufacturing LLC ("iBio Manufacturing") is wholly-owned and incorporated in Delaware

IBIO DO BRASIL BIOFARMACÊUTICA LTDA ("iBio Brazil") is organized in Brazil (99% ownership interest)

iBio CDMO LLC ("iBio CDMO") is registered in Texas and was originally named iBio CMO LLC (99.99% ownership interest). Name was changed effective July 1, 2017.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-233504 and File No. 333-224620), Form S-3 (File No. 333-171315, File No. 333-175420, File No. 333-236735 and File No. 333-200410) and on Form S-8 (File No. 333-229261 and File No. 333-181729) of iBio, Inc. and Subsidiaries of our report, dated October 13, 2020, on our audits of the consolidated financial statements of iBio, Inc. and Subsidiaries as of June 30, 2020 and 2019 and for the years then ended, included in this Annual Report on Form 10-K of iBio, Inc. for the year ended June 30, 2020.

/s/ CohnReznick LLP

Holmdel, New Jersey
October 13, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Thomas F. Isett 3rd, certify that:

1. I have reviewed this Annual Report on Form 10-K of iBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 13, 2020

/s/ Thomas F. Isett 3rd
Thomas F. Isett 3rd
Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, John Delta, certify that:

1. I have reviewed this Annual Report on Form 10-K of iBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 13, 2020

/s/ John Delta
John Delta
Principal Accounting Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of iBio, Inc. (the Company) on Form 10-K for the year ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Thomas F. Isett, Chairman of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

October 13, 2020

/s/ Thomas F. Isett 3rd

Thomas F. Isett 3rd
Chairman and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to iBio, Inc. and will be furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of iBio, Inc. (the Company) on Form 10-K for the year ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, John Delta, Principal Financial Officer and Principal Accounting Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

October 13, 2020

/s/ John Delta
Principal Accounting Officer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to iBio, Inc. and will be furnished to the Securities and Exchange Commission or its staff upon request.