

iBio, Inc.
Form 10-K
October 13, 2010

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

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended June 30, 2010

OR

o 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 000-53125

iBio, Inc.

(Exact name of small business registrant in its charter)
(Formerly iBioPharma, Inc.)

Delaware

26-2797813

*(State or other jurisdiction of
incorporation or organization)*

*(I.R.S. Employer Identification
No.)*

**9 Innovation Way, Suite 100,
Newark, DE**

19711

*(Address of principal executive
offices)*

(Zip Code)

(302) 355-0650

(Registrant's telephone number, including Area Code)

Securities registered under Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

Title of Each Class

Common Stock, \$0.001 par value per share

Edgar Filing: iBio, Inc. - Form 10-K

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 and 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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes

No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Yes

No

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

Large accelerated Filer	<input type="radio"/>
Accelerated Filer	<input type="radio"/>
Non-accelerated Filer	<input type="radio"/>
Smaller reporting company	<input checked="" type="radio"/>

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 stock held by non-affiliates of the Registrant based on the trading price of the Registrant's Common Stock on December 31, 2009 was \$15,888,279.

Edgar Filing: iBio, Inc. - Form 10-K

The number of shares outstanding of each of the Registrant's classes of common equity, as of the latest practicable date:

<i>Class</i>	<i>Outstanding at October 13, 2010</i>
Common Stock, \$0.001 par value	28,272,655 Shares

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III will be incorporated by reference from certain portions of a definitive Proxy Statement which is expected to be filed by the Registrant within 120 days after the close of its fiscal year.

IBIO, INC.
(Formerly iBioPharma, Inc.)

FORM 10-K ANNUAL REPORT

INDEX

	<u>Page</u>
<u>Part I</u>	
<u>Item 1.</u> <u>Business</u>	1
<u>Item 1A.</u> <u>Risk Factors</u>	16
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	30
<u>Item 2.</u> <u>Properties</u>	31
<u>Item 3.</u> <u>Legal Proceedings</u>	31
<u>Item 4.</u> <u>Reserved</u>	31
<u>Part II</u>	
<u>Item 5.</u> <u>Market for Registrant's Common Equity, Related Stockholder Matters and Registrant Purchases of Equity Securities</u>	32
<u>Item 6.</u> <u>Selected Financial Data</u>	33
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	40
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	41
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	41
<u>Item 9A.</u> <u>Controls and Procedures</u>	41
<u>Item 9B.</u> <u>Other Information</u>	42
<u>Part III</u>	
<u>Item 10.</u> <u>Directors, Executive Officers, and Corporate Governance</u>	43
<u>Item 11.</u> <u>Executive Compensation</u>	43
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	43
<u>Item 13.</u> <u>Certain Relationships, Related Transactions, and Director Independence</u>	43
<u>Item 14.</u> <u>Principal Accountant Fees and Services</u>	43
<u>Part IV</u>	
<u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>	44
<u>Signatures</u>	46

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K may constitute 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 (SEC), all as may be amended from time to time. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of iBio, Inc. (the Company) or industry results, to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors including, among others, changes in general economic and business conditions; loss of market share through competition; introduction of competing products by other companies; the timing of regulatory approval and the introduction of new products by the Company; changes in industry capacity; pressure on prices from competition or from purchasers of the Company s products; regulatory obstacles to the introduction of new technologies or products that are important to the Company; availability of qualified personnel; the loss of any significant customers or suppliers; and other factors both referenced and not referenced in this Report. Statements that are not historical fact are forward-looking statements. Forward looking-statements can be identified, by among other things, the use of forward-looking language, such as the words plan , believe , expect , anticipate , intend , estimate , project , will , would , could , should , seeks , or scheduled to , or other similar words, or the negative of these terms or other variations of these terms, or comparable language, or by discussion of strategy or intentions. 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. The Company cautions investors that any forward-looking statements made by the Company are not guarantees or indicative of future performance. Important assumptions and other important factors that could cause actual results to differ materially from those forward-looking statements with respect to the Company include, but are not limited to, the risks and uncertainties affecting their businesses described in Item 1A of this Annual Report on Form 10-K and in other securities filings by the Company.

Although the Company believes that its plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, actual results could differ materially from a projection or assumption in any of its forward-looking statements. The Company s future financial condition and results of operations, as well as any forward-looking statements, are subject to change and inherent risks and uncertainties. The forward-looking statements contained in this Annual Report on Form 10-K are made only as of the date hereof and the Company does not have or undertake any obligation to update or revise any forward-looking statements whether as a result of new information, subsequent events or otherwise, unless otherwise required by law.

PART I

Item 1. Business

Overview

iBio, Inc. (the Company) is a biotechnology company focused on commercializing its proprietary technology, the iBioLaunch platform, for the production of biologics including vaccines and therapeutic proteins. Our strategy is to utilize our technology for development and manufacture of our own product candidates and to work with both corporate and government clients to reduce their costs during product development and meet their needs for low cost, high quality biologics manufacturing systems. Our near-term focus is to establish business arrangements for use of our technology by licensees for the development and production of products for both therapeutic and vaccine uses. Vaccine candidates presently being advanced on our proprietary platform are applicable to newly emerging strains of H1N1 swine-like influenza and H5N1 for avian influenza.

In order to attract appropriate licensees and increase the value of our share of such intended contractual arrangements, we engaged the Center for Molecular Biotechnology of Fraunhofer USA, Inc., or FhCMB, in 2003 to perform research and development activities to develop the platform and to create our first product candidate. We selected a plant-based influenza vaccine for human use as the product candidate to exemplify the value of the platform. Based on research conducted by FhCMB, our proprietary technology is applicable to the production of vaccines for any strain of influenza including the newly-emerged strains of H1N1 swine-like influenza.

In connection with the research and development agreement, FhCMB agreed to use its best efforts to obtain grants from governmental and non-governmental entities to fund additional development of our proprietary plant-based technology. Consequently, in addition to the funding we have provided, FhCMB has received funding from the Bill & Melinda Gates Foundation for development of various vaccines based upon our proprietary technology including an experimental vaccine for H5N1 avian influenza. One of these vaccine candidates began a Phase 1 clinical trial during September 2010.

In addition to the platform and product development engagements, in 2006, the Company engaged FhCMB to create a prototype production module for products made through the use of the platform. The purpose of this engagement was to demonstrate the ease and economy with which platform-based products could be manufactured in order to attract potential licensees and increase the value of our share of such business arrangements. The prototype design, which encompasses the entire production process from the seeding through pre-infiltration plant growth, infiltration with agrobacteria, harvesting of plant tissue and purification of target proteins, was completed in May 2008. A pilot plant based upon this prototype was subsequently constructed in the FhCMB facility in Newark, Delaware. This pilot plant, and the equipment in it, is owned by FhCMB and has been validated for cGMP production. It will be used for cGMP production of protein targets for clinical trials of product candidates utilizing our platform technology.

Edgar Filing: iBio, Inc. - Form 10-K

The Company established non-commercial arrangements among the Company, certain government entities, a non-governmental organization (which we refer to herein as a NGO) and FhCMB, pursuant to which the Company grants non-commercial rights to use its platform for the development and production by FhCMB of product candidates selected by the government entities and NGO, in consideration for grants by the government entities and NGO directly to FhCMB to fund such research and development.

Through (i) the Company/FhCMB contracts and (ii) the non-commercial arrangements described above (which we refer to collectively as the business structure), the Company retains ownership of the intellectual property and exclusive worldwide commercial rights in the fields of human health and veterinary influenza applications of the intellectual property. The Company licenses or otherwise grants use rights (a) to government and NGO entities for not-for-profit applications of the intellectual property for the development or application for which they granted or were granted funding, and (b) to FhCMB for research purposes and applications in other fields.

This business structure helps the Company to enhance the value of commercial rights and the scope of applications of its platform technology. It also helps the Company demonstrate the validity and apparent value of the platform to parties to whom it will offer licenses or other business opportunities. Outsourcing our research and development work allows the Company to develop our product candidates, and thereby promote the value of our platform for licensing and product development purposes, without bearing the full risk and expense of establishing and maintaining its own research and development staff and facilities.

Currently, all of the Company's product candidates are in the preclinical development stage. The Company's platform technology is sometimes referred to as iBioLaunch technology or the iBioLaunch platform, and the category of this technology is sometimes referred to as plant-based technology or as a plant-based platform.

The Company has exclusive control over, and the rights to ownership of, the intellectual property related to all human health and veterinary influenza applications of the plant-based technology developed by FhCMB. Current development projects include conducting proof-of-principle preclinical studies and planning clinical studies of proprietary influenza vaccines.

Many biotech drugs have been on the market long enough for patents on them to expire. Emerging opportunities for biosimilars (also known as biogenerics or follow-on biologics) create potential for our platform technology to be used by potential licensees to enter the market utilizing what the Company expects to be an economical production system. The Company is seeking commercial partners for this category of products and is unlikely to develop products in this category without the financial and marketing support of a commercial partner.

Historically, in addition to the development of the platform technology described in the preceding paragraphs, the Company has also generated sales of nutritional supplements utilizing plants as sources of high-quality nutritional minerals. The Company has a patented process for hydroponic growth of edible plants that causes them to accumulate high levels of important nutritional minerals such as chromium, selenium, iron and zinc. The Company utilized the

Edgar Filing: iBio, Inc. - Form 10-K

services of various wholly-owned subsidiaries of our former parent company, Integrated BioPharma, Inc., (Integrated BioPharma or Former Parent) to support the production, marketing and sales of these phytomineral products.

Effective April 1, 2009, the Company entered into an agreement with IHT Health Products, Inc. (a wholly owned subsidiary of our Former Parent) (IHT) wherein it granted an exclusive license to the Company s patented process in consideration for a royalty of five percent (5%) of net sales and the obligation of IHT to maintain in force and good standing the Company s patent and related intellectual property. At the same time, rights under the existing customer agreements were beneficially transferred to IHT.

In November 2007, the Board of Directors of our Former Parent approved a plan to distribute its equity interests in the Company to its stockholders in the form of a dividend. The record date of the dividend was August 12, 2008 with a distribution date of August 18, 2008. The stockholders of our Former Parent received one share of the Company s common stock for each share of common stock they owned of the Former Parent as of the record date. Immediately following the spin-off, the Company became a public company with stock traded on the OTC Bulletin Board under the symbol IBPM.

Our Business Structure

A key element of our business strategy is to establish business arrangements with licensees to use our platform technology for manufacturing vaccines and therapeutic proteins or for development and commercialization of our product candidates. Thus, we may enter into agreements with other parties to provide them with commercial rights to either our product candidates or with commercial rights to our platform technology itself for manufacturing of their own products.

We believe we can achieve our corporate objectives without employing a large staff, and anticipate maintaining our thinly-staffed employment structure with modest increases in staff as required to develop and support new business relationships. As described above, FhCMB and the Company are currently working within our business structure to develop product candidates based upon our plant-based platform technology pursuant to an agreement that continues until December 31, 2014.

We have been relying upon FhCMB for support in advancing certain of our drug candidates and intend to rely on additional work with possible collaborators during further development and testing of our product candidates. With FhCMB we have been pursuing and obtaining non-dilutive government and non-governmental organization funding directed through FhCMB to provide supplemental funding for applications of our technology. To date, FhCMB has been awarded a total of approximately \$33 million in grants from the Bill & Melinda Gates Foundation for development of product candidates based on the iBioLaunch platform and for research and development of vaccines against influenza, malaria and African sleeping sickness (trypanosomiasis).

Edgar Filing: iBio, Inc. - Form 10-K

In January of 2009, the Company and FhCMB agreed to defer further preparation for clinical trials of a seasonal flu vaccine candidate and instead to focus on clinical trials of a pandemic flu vaccine candidate of interest also to the Bill & Melinda Gates Foundation, which agreed to fund clinical trials of the pandemic flu candidate based upon our platform.

To facilitate the grant and continuing support, we agreed to make our platform technology available to various programs to complete development and provide Global Access to vaccines against influenza, rabies virus, malaria and trypanosomiasis, provided that if the Gates Foundation and FhCMB do not pursue such programs to completion, the subject rights revert to us. The term Global Access means access for people most in need within the developing world in low income and lower-middle-income countries, as identified by the World Bank. Because we have exclusive commercial rights to the technology and these products for human health applications, this grant and any further similar grants would benefit us by enabling FhCMB to enhance the platform technology and expand the information about the technical performance of product candidates derived from our technology. We may decide to commercially license such technology to collaborators for advancement into human clinical evaluation and eventual commercial development.

The U.S. Department of Defense (DoD) has also provided funding to FhCMB for refinement of our technology platform and for preclinical and clinical studies for an anthrax-plague combination vaccine and for an H1N1 influenza vaccine project. To date, FhCMB has received funding and funding commitments for these projects totaling approximately \$37 million. This funding is similarly beneficial to us because we have retained the commercial rights to any technology improvements resulting from those projects.

In summary, the advancement of our technology has indirectly benefited from the funding and funding commitments of research and development activities at FhCMB in recent years by U.S. government and non-governmental organizations in amounts aggregating approximately \$70 million.

Pursuant to the Technology Transfer Agreement between the Company and FhCMB, effective as of January 1, 2004, we paid \$3.6 million to FhCMB to acquire the exclusive rights in intellectual property owned by FhCMB and to obtain from FhCMB maintenance and support necessary to protect the intellectual property through the preparation and filing of patent applications in the United States and around the world. We currently hold four U.S. patents and one international patent. Additionally, we have twelve U.S. and seventy-one international patent applications pending. The latter includes numerous foreign countries including Australia, Brazil Canada, China, Hong Kong, India, Japan, New Zealand, and several countries in Europe. We continue to prepare patent applications relating to our expanding technology in the U.S. and abroad.

Our intellectual property comprises the technology platform pursuant to which hydroponically grown green plants can be used for the accelerated development and manufacture of high-value proteins of interest as candidate therapeutic products and vaccines applicable to a broad range of disease agents, such as influenza, sleeping sickness, anthrax, plague, HPV, and veterinary influenza applications.

By certain subsequent agreements, we engaged FhCMB to perform certain research activities for which we made payments when certain milestone tasks were performed; such payments were conditioned only on the performance of the task, not upon the success or value of what was determined or discovered.

At various times since January 2004, we have amended our agreements with FhCMB. These amendments include a commitment by FhCMB to further develop exclusively for and transfer to us rights to proprietary technology and intellectual property rights in the fields defined in the agreements comprising principally plant-based human vaccines, human antibodies, and human therapeutic proteins and veterinary applications of plant-based influenza vaccines. For these activities, we have committed to make non-refundable payments of \$2.0 million per year for five years, aggregating to \$10.0 million, beginning November 2009. FhCMB is required to expend an additional amount at least equal to the amounts paid by us for the same purposes.

In addition, we are required to make royalty payments to FhCMB equal to 1% of all receipts derived by us from sales of products utilizing the proprietary technology and 15% of all receipts derived by us from licensing the propriety technology to third parties for a period of fifteen years. Minimum annual aggregate payments of \$200,000 are required under the agreement beginning in 2010. In turn, FhCMB is required to pay us royalty payments equal to 9% of all receipts, if any, realized by FhCMB from sales, licensing or commercialization of the intellectual property licensed from us.

We participated with FhCMB from May 2007 through June 2009 on a contract from DARPA (Defense Advanced Research Projects Agency) of the United States Department of Defense for an \$8.5 million project to further enhance our plant-based technology platform for accelerated manufacture of vaccines and antibodies. We served as a sub-contractor to FhCMB and derived revenues of \$1,035,000 during that period. The contract facilitated construction of a pilot manufacturing plant using our platform technology with capacity to provide sufficient materials for clinical trials.

Our Product Candidates

Our short-term focus is to demonstrate the commercial value of our platform technology. A milestone in this process was the scheduling the start of a Phase 1 human clinical trial during late 2010 which will demonstrate the applicability of our platform technology to vaccines for influenza. In addition, in collaboration with FhCMB, we are also developing product candidates for the biodefense market and for infectious diseases important in the developing world such as human papilloma virus.

Seasonal and H1N1 Influenza Vaccines. We believe our technology is applicable to target vaccines directed against seasonal influenza virus strains. Our vaccine candidates have shown significant promise in preclinical efficacy studies in ferrets (the preferred animal model for testing influenza products). In an evaluation of three vaccine candidate formulations in groups of eight ferrets each along with both positive and negative controls, no adverse events were seen in any animals receiving our vaccine candidates. Only one animal receiving one of our vaccine candidates showed any measurable virus shedding which is an important measure of vaccine

effectiveness. These results were as good as the results obtained with positive control animals. The immune responses and protective immunity induced by our vaccine candidates in these animal tests are equivalent to results expected from this type of test to indicate the probability of effectiveness in human subjects. More detail on these tests is available in the scientific paper published in 2008 in the journal *Influenza and Other Respiratory Viruses*, Volume 2, pages 33-40.

We believe our technology is applicable to H1N1 swine-like influenza strains and other seasonal strains, and we expect to modify our product development plans to incorporate H1N1 antigens into any new seasonal vaccine formulation we advance to clinical testing.

Unlike the most common method of producing vaccines against influenza, our process does not rely on chicken eggs and does not require work with whole influenza viruses. Rather, we produce subunit vaccines that are composed of only parts of the protein components of the disease-causing viruses. We believe our subunit vaccines are promising for prevention of influenza infection in humans because they have been demonstrated to prevent influenza infections in ferrets. The ferret is the animal species that is typically used to evaluate a candidate influenza vaccine in laboratory tests before it is tested on humans.

Pandemic Avian Influenza Vaccine. Through FhCMB and their funding from the Gates Foundation, we are developing vaccine candidates targeting highly pathogenic avian influenza (H5N1) viruses based upon the iBioLaunch platform. These candidates have demonstrated immunogenicity and have been successfully tested in mice and ferrets for protective efficacy. Like our candidate vaccines for seasonal influenza, our candidate vaccines for avian influenza are subunit vaccines. Thus, we do not need to culture the intact avian influenza virus in order to produce our candidate vaccines. The Gates Foundation has committed significant funding to FhCMB for preclinical development and a Phase I human clinical trial of this pandemic influenza vaccine candidate using our technology. Our longer term goal is to develop a combined vaccine effective for preventing both seasonal and pandemic influenza infections.

Therapeutic Vaccine for Human Papilloma Virus. We have commercial rights to vaccine candidates developed pursuant to our business structure based on fusing a protein component of HPV called the E7 antigen, to the LicKM protein of the bacterium *Clostridium thermocellum*. Several of these candidate vaccine formulations have demonstrated sufficient immune stimulation and protection from disease in mouse experiments to justify further investment in its development as a potential human therapeutic product. In experimental tests in mice, with each formulation administered to ten mice, some candidates protected all of the mice from the growth of tumors caused by the HPV virus. Additional detail on these experiments was published in 2007 and 2009 in the scientific journal *Vaccine*, 2007; 25(16):3018-3021 and 2009; 27(25-26):3395-3397.

Biodefense Products. We have commercial rights to an oral anthrax booster vaccine candidate developed by FhCMB in collaboration with the Naval Medical Research Center (NMRC). Animal tests have demonstrated safety and efficacy of this product candidate. We also have commercial rights to candidate plague vaccines that FhCMB has demonstrated to be effective in non-human primate tests in which four groups of two monkeys each were inoculated and then

challenged with plague infection. Detailed results of these experiments were published in 2007 in the scientific journal *Vaccine*, 2007 Apr 20; 25(16):3014-7.

As previously indicated, the U.S. Department of Defense (DoD) has also provided funding to FhCMB for refinement of our technology platform and for preclinical and clinical studies for an anthrax-plague combination vaccine and for an H1N1 influenza vaccine project. Specifically, a study in non-human primates demonstrated 100% protection against challenge with anthrax spores, and dose de-escalation studies are currently underway. To date, FhCMB has received funding and funding commitments for these projects totaling approximately \$37 million. This funding is similarly beneficial to us because we have retained the commercial rights to any technology improvements resulting from those projects.

Vaccines for Developing Markets. Funding for developing-world products comes primarily from FhCMB's collaborators, especially the Gates Foundation, and supplements the research and development payments that we make to FhCMB to advance and expand the technology to which we have exclusive commercial rights. This supplemental funding provides significant benefits in technology optimization and is synergistic with our product development programs. Through these developing world programs positive preclinical immunogenicity and efficacy results have been obtained for vaccines for HPV, trypanosomiasis and malaria.

Target Markets

Based on scientific data produced by FhCMB, we believe that our platform technology is well-suited for application to both vaccines and therapeutic proteins. Information on product markets of interest to us is provided in the following paragraphs.

Previously, our business focus was primarily on establishing the data necessary to support commercial licensing of our platform technology for broad protein manufacturing purposes as well as for specific vaccine and therapeutic product candidates. We have long believed that the potential advantages of our technology will enable us to compete effectively against other providers of technology for biotechnology product manufacturing which may be slower, more capital intensive, or more costly to operate. We have initiated a business development program focused on this opportunity as our intellectual property includes proprietary product candidates that may enhance our ability to participate profitably in certain markets.

Vaccine Market. We believe our opportunities to establish commercial collaborations in vaccine markets will arise in two categories: a) Companies interested in tradition vaccine products well established in clinical practice; and b) Governments around the world increasingly committed to achieving autonomy in manufacturing vaccines to protect their citizens from natural outbreaks or deliberate infection. We believe our platform, due to its product flexibility and projected advantages in cost and time of implementation over traditional processes, will be an attractive option for both commercial and government collaborators. The first disease category in which we have focused on demonstrating the applicability of our technology for vaccines is influenza.

Influenza Market. We believe that we can achieve commercial success through establishing commercial collaborations for the use of our iBioLaunch platform technology in the

development of vaccines for prevention of influenza infections and to the establishment of validated technology for rapid response to the outbreak of new strains of influenza. We believe that market demand for influenza vaccines and therapeutics is growing quickly, driven by the pandemic threat of H1N1 swine-like influenza and the continuing threat of a potential pandemic outbreak of avian influenza. Vaccine sales in the seven major markets (US, UK, Germany, France, Italy, Spain and Japan) are expected to more than double to \$5 billion by 2016. These estimates are based on a market analysis conducted by Datamonitor. Datamonitor also states that current manufacturing capacity, even prior to the H1N1 outbreak, is not sufficient to provide enough flu vaccine even for high-risk populations. Consequently, one of the most important challenges facing the industry is the development of novel, faster manufacturing methods that offer higher yields.

We believe that, with further clinical testing and development, the iBioLaunch platform, our proprietary technology platform described in the following paragraphs, will be able to address such a critical need. We have demonstrated the efficiencies of this technology at a laboratory level by producing candidate influenza vaccines in weeks versus the months required for commercially-used chicken egg methods. The yields we have obtained in these laboratory experiments are high enough to be competitive with other methods if we can achieve the same yields and the same time efficiencies on a commercial scale. We, however, have not yet tested our technology at the scale that will be required for commercial use, nor at a scale sufficient to conclude what our commercial cost of goods will be.

Biodefense Vaccine Market. In collaboration with FhCMB and future commercial partners, we expect to participate in the introduction of important new prevention and treatment products as potential countermeasures against bioterrorism threats and for use in the developing world. We do not currently have any commercial partners.

Markets for Therapeutic Proteins. Our technology is broadly applicable to the production of proteins ranging in size and complexity from monoclonal antibodies to smaller proteins such as interferons, growth factors, and enzymes. The potential market for application of our platform to therapeutic proteins is large and can be divided into two types of opportunities: a) Proteins for treatment of orphan diseases; and b) Proteins for bio-similar (bio-generic) products.

Treatment of Orphan Diseases. The worldwide market for orphan disease therapy is over \$80 billion and approximately half of that is addressed through biologic rather than chemical drugs. Well-known products in this category include human enzymes for treatment of lysosomal storage diseases and products for treatment of less-common types of cancer. The incentives for companies to invest in new treatments for smaller patient populations are substantial, both due to tax incentives and also due to the profit margins that are typically seen for these products. To date, the FDA has granted more than 2,000 orphan designations to products in various stages of development. We expect to attract commercial interest in our platform for manufacturing certain orphan biologic drugs from companies that have not yet committed to the more expensive traditional bioreactor alternatives.

Bio-similar Products. The potential market for bio-similar products is large and growing according to industry analysts. Worldwide sales of the eight highest selling patent-protected

products is approximately \$26 billion, and as the patents on these and other products are expiring, interest in competing with generic or bio-similar versions of these well-established clinical products is growing. Due to the efficiency of our platform, we believe we will be able to establish commercial collaborations to participate in this growing market segment.

Research and Development

Our iBioLaunch technology is a platform that uses green plants for the accelerated development and manufacture of high value proteins of immediate interest as product candidates. In addition to therapeutics, we believe that our technology is applicable to vaccines for a broad range of disease agents, based on laboratory experiments conducted to date. We believe we can target rapidly evolving disease agents and develop product candidates that will demonstrate high safety, potency and efficacy. We believe that we will be able to license our iBioLaunch technology to corporations that will scale it up to commercial levels to provide a means of effectively manufacturing pharmaceutical proteins and vaccines.

The iBioLaunch technology is used in a series of steps. First, normal green plants are grown for a few weeks, and at the same time, genes of interest are inserted into proprietary target DNA plasmids. A plasmid is a DNA molecule, usually circular, that can replicate inside a cell, such as a bacterial cell. These plasmids include sequences derived from plant viruses to enable easier activation of genes of interest inside living green plant tissue and also sequences derived from the bacterium, *Agrobacterium tumefaciens*, to enable efficient transfer of the entire vehicle into green plant tissue and activation of the genes once inside. Secondly, once both the plants and the plasmids with the new gene or genes of interest are ready, we transfer the engineered plasmids into plants by first putting them into *Agrobacteria* and then infusing the living *Agrobacteria* into growing green plants where the protein encoded by the new gene can be produced. After the transfer of bacteria into plants, the plants are grown for approximately an additional week and then the plant tissue is harvested and the desired protein or vaccine molecules are extracted and purified.

Because this entire process uses commonly available materials, we are not dependent on unique sources of raw material, nor are we limited to purchasing from single suppliers. The process is fast enough and inexpensive enough to enable more experiments to be conducted in a given period of time than can usually be conducted with slower or more expensive technology such as cultured animal cells and bioreactor methods. A more technically detailed description of this technology and its use was published in 2007 in the scientific journal *Influenza and Other Respiratory Viruses*, volume 1, pages 19-25. Note that in this publication, the term iBioLaunch is not used to describe the technology because that commercial designation was created after the publication of these scientific data.

Because our iBioLaunch technology has proven useful at a laboratory level in the production of high value proteins of immediate interest as product candidates, we believe it can be applied to commercial product development and biologic pharmaceutical manufacturing. Advantages of our platform technology include its short development time-frame for the harvesting of the applicable protein or vaccine molecules and applicability to a broad range of disease agents. This has enabled us, at a laboratory level, to target rapidly evolving disease agents and develop

Edgar Filing: iBio, Inc. - Form 10-K

product candidates which have demonstrated high safety, potency and efficacy in laboratory animal tests.

The table below summarizes the results of tests conducted to date to assess the breadth of applicability of our platform technology. Some, but not all, of the listed targets are currently being pursued as product candidates by us to document the effectiveness of our platform technology. However, this table is presented to illustrate the breadth of applicability of our technology, rather than as a list of products under active development.

Target	Produced via iBioLaunch	<i>In vitro</i> characterization complete	Immunogenicity demonstrated in animal model	Efficacy demonstrated in animal model
Influenza (vaccine)	X	X	X	X
Anthrax (vaccine)	X	X	X	X
Plague (vaccine)	X	X	X	X
RSV (vaccine)	X	X	X	X
Malaria (vaccine)	X	X	X	UT
Trypanosomes (vaccine)	X	X	X	X
HPV (vaccine)	X	X	X	X
Measles (vaccine)	X	X	X	UT
Influenza antibody (therapeutic/diagnostic)	X	X	NA	UT
Anthrax antibody (therapeutic)	X	X	NA	X
Tetanus toxin antibody (therapeutic)	X	X	NA	UT
hGH (therapeutic)	X	X	NA	UT
GM-CSF (therapeutic)	X	X	NA	UT
Diabetes autoantigen (diagnostic)	X	X	NA	UT

NA = not applicable UT = untested

We currently are prioritizing H1N1 influenza vaccine candidates for our in-house research and development portfolio.

During the years ended June 30, 2010 and 2009, we incurred research and development expenses of \$2,517,000 and \$847,000, respectively.

Intellectual Property

We exclusively control intellectual property developed at FhCMB for human health applications of plant-based production and protein expression systems. We also exclusively control the veterinary field for plant-made influenza vaccines. Our success will depend in part on our ability to obtain and maintain patent protection for our technologies 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 currently hold four U.S. patents and one international patent. Additionally, we have twelve U.S. and seventy-one international patent applications pending. The latter includes numerous foreign countries including Australia, Brazil Canada, China, Hong Kong, India, Japan, New Zealand, and several countries in Europe. We continue to prepare patent applications relating to our expanding technology in the U.S. and abroad.

The following summarizes the areas covered by our issued and pending patent applications:

Issued Technology Filing (U.S.)

- o Virus-induced gene silencing in plants
- o Transient expression of foreign genes in plants

Pending Technology Filings (U.S. and International)

- o Virus-induced gene silencing in plants (International)
- o Activation of transgenes in plants by viral vectors
- o Protein production in seedlings
- o Agroinfiltration of plants with launch vector
- o Transient expression of proteins in plants
- o Thermostable carrier molecule
- o Protein expression in clonal root cultures

Pending Product Filings (U.S. and International)

- o Antibodies
- o Influenza vaccines
- o Influenza therapeutic antibodies
- o Anthrax vaccines
- o Plague vaccine
- o HPV vaccines
- o Trypanosomiasis vaccine

Sales and Marketing

We currently expect to obtain Phase 1 or equivalent human clinical data on the first human test of a product produced with our platform before negotiating license or marketing agreements for

that or other product candidates. In some cases, by bearing the initial product development risk ourselves, we expect to be able to negotiate more favorable terms with our partners, and to achieve a higher return on investment than would be possible with commercial agreements negotiated at an earlier stage of development. However, in other cases, especially where clinical characteristics of a candidate product are well known such as for a bio-similar candidate, we anticipate our commercial partner bearing substantially all of the clinical development costs of their product produces using our platform.

We believe our technology platform will be attractive to other parties for vaccine and therapeutic protein manufacturing purposes. We anticipate marketing our technology for such purposes and plan to provide commercial technology transfer services to such third-party licensees if we are successful in negotiating such arrangements.

FhCMB has demonstrated efficacy of an anthrax vaccine candidate and an anthrax-plague combination vaccine candidate in relevant animal model challenge studies. With funding from government sources, we plan to complete preclinical studies required for human safety evaluation. Our strategy for introduction of these products into the market includes partnership with one or more firms experienced in biodefense product commercialization and federal government procurement. We have not yet begun negotiations to obtain such a partnership arrangement.

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 may develop based on the use of our platform technology.

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. Several large pharmaceutical companies are currently already in the seasonal influenza vaccine business, and are likely to enter the market with new H1N1 vaccines produced with conventional technology. In addition, Protein Sciences Corporation was awarded a U.S. government contract to develop a new H1N1 vaccine based on its insect virus technology. Five injectable influenza vaccines are approved for use in the U.S. These include Afluria made by CSL Limited, Fluzone made by Sanofi-Pasteur, Fluarix made by GlaxoSmithKline, Flulaval made by ID Biomedical and distributed by GlaxoSmithKline, and Fluvirin made by Novartis. In addition, a nasally-administered influenza vaccine called FluMist is made by MedImmune. If we are successful in obtaining regulatory approval for our influenza vaccine candidate, we would have to compete against these large companies.

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 platform technology for the purposes of establishing license agreements. For example,

Novavax is developing vaccines for influenza, based on the use of cultured insect cells. Its candidate products are more advanced in development than ours are and have already demonstrated positive results in human clinical trials. Similarly, Medicago has conducted a Phase I clinical study of an influenza vaccine produced in green plants. Other companies, such as Vical, are attempting to develop vaccines based on the use of nucleic acids rather than proteins. If these efforts are successful in clinical trials, nucleic acid based vaccine products may compete effectively against our products and may potentially prevent us from being able to obtain commercial agreements or partnerships to enter the market.

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 therapies for the diseases and conditions addressed by our vaccine and therapeutic protein candidates that are undergoing clinical trials and for the diseases and conditions that are subjects of our preclinical development program. 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 platform for commercial product candidates are likely to be efficacy, safety profile, price, and convenience.

Government Regulation and Product Approval

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacture and marketing of pharmaceutical drugs and vaccines. All of the vaccine, therapeutic or diagnostic products developed from our platform technology 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 Food & 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 pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require 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, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown

Edgar Filing: iBio, Inc. - Form 10-K

problems that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Please see **Risk Factors** for additional information on the regulatory risks we face in attempting to develop products for human use.

Before testing any compounds with potential therapeutic value in human subjects in the U.S., 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 a drug and its formulation. *In vitro* refers to tests conducted with cells in culture and *in vivo* refers to tests conducted in animals. 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 Investigational New Drug application (IND) 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 trials in human volunteers. In the case of candidate vaccine products, 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.

In order to test a new biologic product or vaccine in humans in the U.S., an IND must be filed with the FDA. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concern or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can 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>.

Any products we or a licensee manufactures or distributes under FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMPs (current Good Manufacturing Practices), which are the standards the FDA requires be met during the manufacturing of drugs and biologic products, and which impose procedural and documentation requirements upon us and any third party manufacturers we utilize.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our product candidates. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

The product testing and clinical trial requirements that must be met before a product candidate can be marketed are substantial, time-consuming, and require investments of millions of dollars per product candidate. We must test our vaccine candidates for safety in Phase I clinical trials. Vaccine candidates for use in preventing disease will be administered to healthy people, and,

therefore, the standards for safety and the requirement for absence of unwanted side-effects are high. In addition to demonstrating safety, we must also demonstrate that our vaccine candidates are capable of stimulating an immune response in human subjects that convinces knowledgeable scientists and physicians that the vaccine candidate is likely to be beneficial in inducing protective immunity against the disease of interest. We must then demonstrate in humans that subjects receiving our vaccine candidate develop the disease of interest at a lower rate than subjects who do not receive our candidate. In addition, when a product is already available for use in the United States, such as vaccines for prevention of influenza infection, we must demonstrate that our vaccine candidate is not inferior to the available product.

Product Liability

Our business involves exposure to potential product liability risks that are inherent in the development, manufacture, and sale of pharmaceutical products.

Prior to our spin-off from Integrated BioPharma, we maintained product liability insurance for sales of our phytomineral products through Integrated BioPharma's product liability insurance policy at \$5.0 million per occurrence with a \$5.0 million aggregate. Our sales of phytomineral products continued to be covered under Integrated BioPharma's product liability policy through April 1, 2009 when, as previously discussed, we entered into an agreement with a subsidiary of Integrated BioPharma wherein we granted an exclusive license to that subsidiary to manufacture and sell phytomineral products produced using our patented process in consideration for a royalty of five percent (5%) of net sales. We will need to purchase our own product liability insurance policy to cover any of our clinical trial and product liability risks. We anticipate that our product liability coverage will be at least comparable to our prior coverage. However,

We may not be able to obtain product liability insurance for future trials;

We may not be able to obtain product liability insurance for future products;

We may not be able to maintain product liability insurance on acceptable terms;

We may not be able to secure increased coverage as the commercialization of our technology proceeds; or

Our insurance may not provide adequate protection against potential liabilities.

Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Defending a lawsuit would be costly and significantly divert management's attention from conducting our business. If third parties were to bring a successful product liability claim or series of claims against us for uninsured liabilities or in excess of insured liability limits, our business, financial condition and results of operations could be materially harmed.

Employees

As of October 13, 2010, we had three full-time and two part-time employees. Our employees are not represented by any union and are not the subject of a collective bargaining agreement. We believe that we have a good relationship with them and expect their numbers to increase by two or three full-time employees during the next twelve months as we continue to develop the infrastructure necessary to advance our business interests. Since our business strategy is based on outsourcing our development and clinical trial work to third parties, we believe this staffing level will be sufficient to meet our needs.

Available Information

We are required to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). These filings are available to the public via the Internet at the SEC's website located at <http://www.sec.gov>. You may also read and copy any document we file with the SEC at the SEC's public reference room located at 450 Fifth Street, N.W., Washington, D.C. 20549. For more information, please call the SEC at 1-800-SEC-0330.

Our website is located at www.ibioinc.com. You may request a copy of our filings with the SEC (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

iBio, Inc.
9 Innovation Way, Suite 100
Newark, Delaware 19711
Tel: 302-355-0650
Attn: Investor Relations

Item 1A. Risk Factors

Our 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 prospectus, the following risks 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. 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.

Risks Related to Our Business

Our plant-based technology platform has not previously been used by others to successfully develop commercial products, and if we are not able to establish licenses of the platform, we may not generate sufficient license revenues to fulfill our business plan.

If we are unable to convince others to adopt the use of the platform in addition to or instead of other methods to produce vaccines and therapeutic proteins, we will not generate the revenues presently contemplated by our business plan to support our continuing operations.

The majority of our product candidates are in the preclinical stage of development, and if we or our licensees are not able to successfully develop and commercialize them, we may not generate sufficient revenues to fulfill our business plan.

We have internal product candidates and believe our technology to be applicable to the product candidates of other companies. Our success in establishing licenses to our platform will substantially depend on our or our clients' successful completion of clinical trials, and obtaining required regulatory approvals for our product candidates alone or with other persons. If the studies described above or any further studies fail, if we do not obtain required regulatory approvals, or if we fail to commercialize any of our product candidates alone or with licensees, we may be unable to generate sufficient revenues to attain profitability or continue our business operations, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decline and your holdings of our stock to lose most, if not all, of their value.

Our licensees will not be able to commercialize product candidates based on our platform technology 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. 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 technology, including the following:

Our licensees' preclinical or clinical trials may produce negative or inconclusive results, which may require additional preclinical testing or clinical trials or the abandonment of projects that we expect to be promising. For example, promising animal data may be obtained about the immunogenicity of a vaccine candidate and then human tests may result in no or inadequate immune responses. In addition, unexpected safety concerns may be encountered that would require further testing even if the vaccine candidate produced a very significant immune 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 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.

Our licensee might have to suspend or terminate clinical trials if the participating patients 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 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 our licensee's 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 our licensees do and impair our ability to commercialize our technology platform or products or product candidates based on our technology platform. Poor clinical trial results or delays may make it impossible to license a product or so reduce its attractiveness to a licensing partner that we will be unable to successfully commercialize a product.

We will need substantial additional funding to execute our business plan and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our commercialization efforts.

We will need substantial additional funding and may be unable to raise capital when needed or may be unable to raise capital on attractive terms, which would force us to delay, reduce or eliminate our technology development programs or commercialization efforts.

We believe that our existing cash resources, along with our \$3.0 million private placement of common stock that closed in September 2009, as described herein, and support from FhCMB collaborators, will be sufficient to meet our projected operating requirements only through the balance of calendar 2010. Our future funding requirements will depend on many factors, including:

Our ability to advance product candidates based on our technology into development with licensees;

The success of our anticipated commercial agreements with licensees;

Our ability to establish and maintain additional development agreements or other alternative arrangements;

The timing of, and the costs involved in, obtaining regulatory approvals;

The cost of manufacturing activities;

The cost of commercialization activities, including marketing, sales and distribution;

The costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including, if necessary, litigation costs and the results of such litigation; and

Potential acquisition or in-licensing of other products or technologies.

If we are unsuccessful in raising additional capital or other alternative financing, we might have to defer or abandon our efforts to commercialize the intellectual property obtained from FhCMB and cease operations.

Our product development and commercialization involve a number of uncertainties, and we may never generate sufficient revenues from the sale of potential products to become profitable; therefore, we may raise funds which may be dilutive of our shareholders in the future.

We have generated no significant revenues to date. To generate revenue and to achieve profitability, we must successfully develop licenses for our platform and/or clinically test, market and sell our potential products. Even if we generate revenue and successfully achieve profitability, we cannot predict the level of that profitability or whether it will be sustainable. We expect that our operating results will fluctuate from period to period as a result of differences in when we incur expenses and receive revenues from sales of our potential products, business arrangements and other sources. Some of these fluctuations may be significant.

Until we can generate a sufficient amount of license and/or product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings and corporate product or technology development agreements and licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through development and licensing arrangements with third parties, it will be necessary to relinquish valuable rights to our technologies, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Even if we or our potential licensees successfully complete clinical trials for our product candidates, there are no assurances that we will be able to submit, or obtain FDA approval of, a new drug application or biologics license application.

There can be no assurance that, if clinical trials for any product candidates are successfully completed, either we or our licensees will be able to submit a biologics license application (BLA), to the FDA or that any BLA submitted will be approved by the FDA in a timely manner, if at all. After completing clinical trials for a product candidate in humans, a dossier is prepared and submitted to the FDA as a BLA, and includes all preclinical and clinical trial data that clearly establish both short-term and long-term safety for a product candidate, and data that establishes the statistically significant efficacy of a product candidate, in order to allow the FDA to review such dossier and to consider a product candidate for approval for commercialization in the United States. If we are unable to submit a BLA with respect to any of our product candidates, or if any BLA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and requires additional clinical trials, even when product candidates perform well or achieve favorable results in large-scale Phase 3 clinical trials. If we or our licensees fail to commercialize any product candidates based on our technology, we may be unable to generate sufficient revenues to continue operations or attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to significantly decrease.

We face competition from many different sources, including pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions, and such competition may adversely affect our ability to generate revenue from our products.

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.

Other companies may also prove to be significant competitors, particularly through arrangements with large and established companies, and this may reduce the value of our platform technology for the purposes of establishing license agreements. For example, Novavax is developing vaccines for influenza, based on the use of cultured insect cells. Its candidate products are more advanced in development than ours are and have already demonstrated positive results in human clinical trials. Similarly, Medicago has announced preclinical experiments to produce influenza vaccines in green plants. Other companies, such as Vical, are attempting to develop vaccines based on the use of nucleic acids rather than proteins. If these efforts are successful in clinical trials, nucleic acid based vaccine technology may compete effectively against our technology platform and may potentially prevent us from being able to obtain commercial agreements or partnerships.

There are currently approved therapies for the diseases and conditions addressed by our vaccine and antibody candidates that are undergoing clinical trials and for the diseases and conditions that are subjects of our preclinical development program. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products based on other technology platforms that are safer, more effective, have fewer side effects or are less expensive than any products that we or our licensees may develop.

Finally, 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 will depend significantly on arrangements with third parties to develop and commercialize our product candidates.

A key element of our business strategy is to establish arrangements with licensees to develop and commercialize product candidates. We and FhCMB currently are working within our business structure, which includes non-commercial arrangements as described above, to apply further our plant-based platform technology. Delays, withdrawals or other adverse changes to the current participants in our business structure might adversely affect our ability to develop and commercialize our product candidates.

We expect to rely upon our future business arrangements for support in advancing certain of our drug candidates and intend to rely on additional work under current and future arrangements during our efforts to commercialize our product candidates. Our contractors may be conducting multiple product development efforts within the same disease areas that are the subjects of their agreements with us. Our agreements might not preclude them from pursuing development efforts

Edgar Filing: iBio, Inc. - Form 10-K

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 contractor.

The success of our business arrangements will depend heavily on the efforts and activities of the organizations which are party to these arrangements. Our future contractual arrangements may provide significant discretion in determining the efforts and resources available to these programs. The risks that we face in connection with these arrangements, and that we anticipate being subject to in future arrangements, include the following:

Future agreements may be for fixed terms and subject to termination under various circumstances, including, in some cases, on short notice without cause.

Our future licensees may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the agreement with us.

Our future licensees may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products.

Our future licensees may not properly maintain or defend our intellectual property rights, or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential liability.

Our future licensees may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries. The ability of our product candidates and products to reach their potential could be limited if our licensees or customers decrease or fail to increase spending relating to such products.

Business arrangements with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Such terminations or expirations would adversely affect us financially and could harm our business reputation.

We have no experience in the sales, marketing and distribution of pharmaceutical products or in commercial technology transfer operations.

If we fail to establish commercial licenses for our platform technology or fail to enter into arrangements with partners with respect to the sales and marketing of any of our future potential product candidates, we would need to develop a sales and marketing organization with supporting distribution capability in order to directly market our technology and/or related

products. Significant additional expenditures would be required for us to develop such an in-house sales and marketing organization.

We may not be successful in establishing additional arrangements with third parties, which could adversely affect our ability to discover, develop and commercialize products.

We engaged FhCMB to perform research and development activities to apply our platform technology to create product candidates. We currently do not have other similar agreements with third parties. If we are able to obtain such agreements, however, these arrangements may not be scientifically or commercially successful. If we are unable to reach new agreements with suitable third parties, we may fail to meet our business objectives for the affected product or program. We face significant competition in seeking appropriate companies with which to create additional similar business structures. Moreover, these arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish additional alternative arrangements. The terms of any additional arrangements that we establish may not be favorable to us. Moreover, these arrangements may not be successful.

If third parties on whom we or our licensees will rely for 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 clinical trials required to obtain regulatory approval for our products. We have not yet contracted with any third parties to conduct our clinical trials. 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 and expect to continue to do so. 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 may 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.

We face substantial uncertainty in our ability to protect our patents and proprietary technology.

Our ability to commercialize our products will depend, in part, on our ability to obtain patents, to enforce those patents and preserve trade secrets, and to operate without infringing on the proprietary rights of others.

The patent positions of biotechnology companies like us are highly uncertain and involve complex legal and factual questions.

We currently hold four U.S. patents and one international patent. Additionally, we have twelve U.S. and seventy-one international patent applications pending. The latter includes numerous foreign countries including Australia, Brazil, Canada, China, Hong Kong, India, Japan, New

Zealand, and several countries in Europe. We continue to prepare patent applications relating to our expanding technology in the U.S. and abroad.

There can be no assurance that:

Patent applications owned by or licensed to us will result in issued patents;

Patent protection will be secured for any particular technology;

Any patents that have been or may be issued to us will be valid or enforceable;

Any patents will provide meaningful protection to us;

Others will not be able to design around the patents; or

Our patents will provide a competitive advantage or have commercial application.

The failure to obtain and maintain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing of any product. Please see [Our Business](#) [Intellectual Property](#) for more information.

We cannot assure you that our patents will not be challenged by others.

There can be no assurance that patents owned by or licensed to us will not be challenged by others. We currently hold one issued U.S. patent for methods of inducing gene silencing in plants and one U.S. patent application for which we have received a notice of allowance, describing systems for expression of vaccine antigens in plants. Please see [Our Business](#) [Intellectual Property](#) for more information on our current patents and patent applications. We could incur substantial costs in proceedings, including interference proceedings before the United States Patent and Trademark Office and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our or our licensors' inventions and products, as well as about the enforceability, validity or scope of protection afforded by the patents. Any adverse decisions about the patentability of our product candidates could cause us to either lose rights to develop and commercialize our product candidates or to license such rights at substantial cost to us. In addition, even if we were successful in such proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information, may not adequately protect our intellectual property, and will not prevent third parties from independently discovering technology similar to or in competition with our intellectual property.

We rely on trade secrets and other unpatented proprietary information in our product development activities. To the extent we rely on trade secrets and unpatented know-how to maintain our competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. We seek to protect trade secrets and proprietary knowledge, in part, through confidentiality agreements with our employees, consultants, advisors, collaborators and contractors. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information. If our employees, scientific consultants, advisors, collaborators or contractors develop inventions or processes independently that may be applicable to our technologies, product candidates or products, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. If we fail to obtain or maintain trade secret protection for any reason, the competition we face could increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business.

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our customers, collaborators or licensees that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our customers, collaborators or licensees may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our customers, collaborators or licensees were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our customers, collaborators or licensees are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.

Clinical trial and product liability insurance is volatile and may become increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

Liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;

An increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;

Withdrawal of clinical trial volunteers or patients;

Damage to our reputation and the reputation of our products, resulting in lower sales of any future commercialized product which we may have;

Regulatory investigations that could require costly recalls or product modifications;

Litigation costs; or

The diversion of management's attention from managing our business.

Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. If third parties were to bring a successful product liability

claim or series of claims against us for uninsured liabilities or in excess of insured liability limits, our business, financial condition and results of operations could be materially harmed.

The agreements we entered into with Integrated BioPharma in connection with the distribution could restrict our operations.

In connection with the August 2008 spin-off transaction that resulted in our becoming a separate, publicly-traded company, we and our former parent, Integrated BioPharma, entered into a number of agreements that govern the spin-off and our future relationship. Each of these agreements were entered into in the context of our relationship to Integrated BioPharma as a subsidiary and our spin-off from Integrated BioPharma and, accordingly, the terms and provisions of these agreements may be less favorable to us than terms and provisions we could have obtained in arm's-length negotiations with unaffiliated third parties. These agreements commit us to take actions, observe commitments and accept terms and conditions that are or may be advantageous to Integrated BioPharma but are or may be disadvantageous to us.

The terms of these agreements include obligations and restrictive provisions include, but are not limited to, agreement to indemnify Integrated BioPharma, its affiliates, and each of their respective directors, officers, employees, agents and representatives from certain liabilities arising out of any litigation we are involved in and all liabilities that arise from our breach of, or performance under, the agreements we are entered into with Integrated BioPharma in connection with the distribution and for any of our liabilities.

Current economic conditions may cause a decline in business spending which could adversely affect our business and financial performance.

Our operating results are impacted by the health of the North American economies. Our business and financial performance, including collection of our accounts receivable, recoverability of assets including investments, may be adversely affected by current and future economic conditions, such as a reduction in the availability of credit, financial market volatility, recession, et cetera. Additionally, we may experience difficulties in scaling our operations to react to economic pressures in the U.S.

Our independent registered public accounting firm identified a material weakness in our internal control over financial reporting.

Our independent registered public accounting firm, J.H. Cohn LLP (JHC), communicated to our audit committee on February 10, 2010 that a material weakness existed in our internal control over financial reporting. This weakness was comprised of financial accounting and disclosure deficiencies and financial reporting deficiencies for non-routine, complex transactions. This weakness resulted in additions and corrections to disclosures in our Form 10-Q prior to filing and in us not implementing the guidance in ASC 815-40, Derivative and Hedging Contracts in an Entity's Own Equity in a timely manner, which required the restatement of our financial statements as of and for the quarter ended September 30, 2009. Upon receipt of the communication from JHC, management took immediate action to prospectively remediate this weakness by establishing an in-depth independent internal review that did not previously exist.

Failure in the remediation of this weakness could diminish our ability to meet our financial reporting obligations in an accurate and timely manner.

Risks Relating to our Common Stock

We need additional financing to execute our business plan which may not be available on commercially acceptable terms, if at all. If we are unable to obtain such financing, we will be required to delay, scale back, or eliminate part or all of our operations and may not continue as a going concern.

We have limited financial resources and incurred net losses during the fiscal years ended June 30, 2010 and 2009. We need to obtain additional financing to meet our working capital needs and execute our business plan.

Our independent registered public accounting firm has concluded that our losses, negative cash flow, accumulated deficit, and negative working capital as of and for the year ended June 30, 2010 raise substantial doubt about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our independent registered public accounting firm may make it more difficult for us to secure financing on terms acceptable to us, if at all, and likely may adversely affect the terms of any financing that we may obtain.

If we are unable to raise funds when required or on acceptable terms, we may have to: a) Significantly delay, scale back, or discontinue the development and/or commercialization of one or more product candidates; b) Seek collaborators for product candidates at an earlier stage than would otherwise be desirable and/or on terms that are less favorable than might otherwise be available; or c) Relinquish or otherwise dispose of rights to technologies, product candidates, or products that we would otherwise seek to develop or commercialize ourselves and/or cease operations.

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

It is possible 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.

Our common stock is considered a penny stock and may be difficult to sell.

The SEC has adopted regulations which generally define penny stock to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. As the market price of our common stock has been less than \$5.00 per share, our common stock is considered a penny stock according to SEC rules.

Edgar Filing: iBio, Inc. - Form 10-K

This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of investors to sell their shares. In addition, since our common stock is currently traded on the OTC Bulletin Board, investors may find it difficult to obtain accurate quotations for our common stock and may experience a lack of buyers to purchase such stock or a lack of market makers to support the stock price.

Provisions in our charter documents 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 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 protects the continuity of our management. Specifically, if in the due exercise of his/her or 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 block 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. 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.

We also are subject to Section 203 of the Delaware General Corporation Law. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless the transaction in which the person became an interested stockholder is approved in a manner presented in Section 203 of the Delaware General Corporation Law. Generally, a business combination is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of a corporation's

voting stock. This statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Facilities

Our facilities currently consist of approximately 500 square feet of office space at our headquarters located in Newark, Delaware, which is leased on a month-to-month basis from FhCMB. In this space, we perform or maintain oversight of our administrative, clinical development, regulatory affairs and business development functions.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 4. Reserved

PART II

Item 5. Market for Common Equity, Related Stockholder Matters and Registrant Purchases of Equity Securities**Market Information**

On August 18, 2008 immediately after the spin-off from Integrated BioPharma, the Company's common stock commenced trading on the OTC Bulletin Board under the symbol IBPM.

The following table shows the reported high and low closing prices per share for our common stock during the fiscal years ended June 30, 2010 and 2009:

	2010		2009	
	High	Low	High	Low
First quarter	\$ 1.25	\$ 0.38	\$ 2.00	\$ 1.00
Second quarter	\$ 1.44	\$ 0.75	\$ 1.00	\$ 0.11
Third quarter	\$ 1.22	\$ 0.57	\$ 0.31	\$ 0.12
Fourth quarter	\$ 1.42	\$ 0.95	\$ 0.69	\$ 0.20

 Holders

As of October 13, 2010, we had approximately 1,000 holders of record of our common stock.

Dividends

The Company has not declared or paid a dividend with respect to its common stock during the fiscal years ended June 30, 2009 and 2010 nor does the Company anticipate paying dividends in the foreseeable future.

Equity Compensation Plans

The following table provides information regarding the status of our existing equity compensation plans at June 30, 2010:

	Number of Shares of Common Stock to be Issued Upon Exercise of Outstanding Options and Warrants	Weighted Average Exercise Price of Outstanding Options and Warrants	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the previous columns)
Equity compensation plans approved by stockholders	2,210,000	\$ 0.58	7,790,000
Equity compensation plans not approved by stockholders			
Total	2,210,000	\$ 0.58	7,790,000

Item 6. Selected Financial Data

Not Applicable

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

Forward-Looking Statements

You should read the following discussion of our results of operations and financial condition in conjunction with the financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion includes forward-looking statements and you should read the section titled "Disclosure Regarding Forward-Looking Statements" appearing at the beginning of this Annual Report on Form 10-K for a description of the risks and assumptions associated with such statements.

Overview

iBio, Inc. (the Company) is a biotechnology company focused on commercializing its proprietary technology, the iBioLaunch platform, for the production of biologics including vaccines and therapeutic proteins. Our strategy is to utilize our technology for development and manufacture of our own product candidates and to work with both corporate and government clients to reduce their costs during product development and meet their needs for low cost, high quality biologics manufacturing systems. Our near-term focus is to establish business arrangements for use of our technology by licensees for the development and production of products for both therapeutic and vaccine uses. Vaccine candidates presently being advanced on our proprietary platform are applicable to newly emerging strains of H1N1 swine-like influenza and H5N1 for avian influenza.

In order to attract appropriate licensees and increase the value of our share of such intended contractual arrangements, we engaged the Center for Molecular Biology of Fraunhofer USA, Inc., or FhCMB, in 2003 to perform research and development activities to develop the platform and to create our first product candidate. We selected a plant-based influenza vaccine for human use as the product candidate to exemplify the value of the platform. Based on research conducted by FhCMB, our proprietary technology is applicable to the production of vaccines for any strain of influenza including the newly-emerged strains of H1N1 swine-like influenza.

In connection with the research and development agreement, FhCMB agreed to use its best efforts to obtain grants from governmental and non-governmental entities to fund additional development of our proprietary plant-based technology. Consequently, in addition to the funding we have provided, FhCMB has received funding from the Bill & Melinda Gates Foundation for development of various vaccines based upon our proprietary technology including an experimental vaccine for H5N1 avian influenza. One of these vaccine candidates is scheduled to begin Phase 1 clinical trials during late calendar year 2010.

Edgar Filing: iBio, Inc. - Form 10-K

In addition to the platform and product development engagements, in 2006, the Company engaged FhCMB to create a prototype production module for products made through the use of the platform. The purpose of this engagement was to demonstrate the ease and economy with which platform-based products could be manufactured in order to attract potential licensees and increase the value of our share of such business arrangements. The prototype design, which encompasses the entire production process from the seeding through pre-infiltration plant growth, infiltration with agrobacteria, harvesting of plant tissue and purification of target proteins, was completed in May 2008. A pilot plant based upon this prototype was subsequently constructed in the FhCMB facility in Newark, Delaware. This pilot plant, and the equipment in it, is owned by FhCMB and has been validated for cGMP production. It will be used for cGMP production of protein targets for clinical trials of product candidates utilizing our platform technology.

The Company established non-commercial arrangements among the Company, certain government entities, a non-governmental organization (which we refer to herein as a NGO) and FhCMB, pursuant to which the Company grants non-commercial rights to use its platform for the development and production by FhCMB of product candidates selected by the government entities and NGO, in consideration for grants by the government entities and NGO directly to FhCMB to fund such research and development.

Through (i) the Company/FhCMB contracts and (ii) the non-commercial arrangements described above (which we refer to collectively as the business structure), the Company retains ownership of the intellectual property and exclusive commercial rights in the fields of human health and veterinary influenza applications of the intellectual property. The Company licenses or otherwise grants use rights (a) to government and NGO entities for not-for-profit applications of the intellectual property for the development or application for which they granted or were granted funding, and (b) to FhCMB for research purposes and applications in other fields.

This business structure helps the Company to enhance the value of commercial rights and the scope of applications of its platform technology. It also helps the Company demonstrate the validity and apparent value of the platform to parties to whom it will offer licenses or other business opportunities. Outsourcing our research and development work allows the Company to develop our product candidates, and thereby promote the value of our platform for licensing and product development purposes, without bearing the full risk and expense of establishing and maintaining its own research and development staff and facilities.

Currently, all of the Company's product candidates are in the preclinical development stage. The Company's platform technology is sometimes referred to as iBioLaunch technology or the iBioLaunch platform, and the category of this technology is sometimes referred to as plant-based technology or as a plant-based platform.

The Company has exclusive control over and the rights to ownership of the intellectual property related to all human health and veterinary influenza applications of the plant-based technology developed by FhCMB. Current development projects include conducting proof-of-principle preclinical studies and planning clinical studies of proprietary influenza vaccines.

Edgar Filing: iBio, Inc. - Form 10-K

Many biotech drugs have been on the market long enough for patents on them to expire. Emerging opportunities for biosimilars (also known as biogenerics or follow-on biologics) create potential for our platform technology to be used by potential licensees to enter the market utilizing what the Company expects to be an economical production system. The Company is seeking commercial partners for this category of products and is unlikely to develop products in this category without the financial and marketing support of a commercial partner.

Historically, in addition to the development of the platform technology described in the preceding paragraphs, the Company has also generated sales of nutritional supplements utilizing plants as sources of high-quality nutritional minerals. The Company has a patented process for hydroponic growth of edible plants that causes them to accumulate high levels of important nutritional minerals such as chromium, selenium, iron and zinc. The Company utilized the services of various wholly-owned subsidiaries of our former parent company, Integrated BioPharma, Inc., (Integrated BioPharma or Former Parent) to support the production, marketing and sales of these phytomineral products.

Effective April 1, 2009, the Company entered into an agreement with IHT Health Products, Inc. (a wholly owned subsidiary of our Former Parent) (IHT) wherein it granted an exclusive license to the Company's patented process in consideration for a royalty of five percent (5%) of net sales and the obligation of IHT to maintain in force and good standing the Company's patent and related intellectual property. At the same time, rights under the existing customer agreements were beneficially transferred to IHT.

In November 2007, the Board of Directors of our Former Parent approved a plan to distribute its equity interests in the Company to its stockholders in the form of a dividend. The record date of the dividend was August 12, 2008 with a distribution date of August 18, 2008. The stockholders of our Former Parent received one share of the Company's common stock for each share of common stock they owned of the Former Parent as of the record date. Simultaneously, the Company converted \$7.9 million in debt due to the Former Parent into common stock and raised \$5.0 million through the sale of common stock to fund operations. Immediately following the spin-off: a) The Former Parent owned 5.4% of the Company's common shares and ceased to control the Company; and b) The Company became a public company with stock traded on the OTC Bulletin Board under the symbol IBPM.

These financial statements were prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to do so is dependent upon our ability to obtain additional equity or debt financing, reduce expenditures, and/or generate revenue. These financial statements do not include any adjustments that might result from the outcome of that uncertainty.

Current cash and working capital resources are expected to support our activities through the balance of calendar 2010. We plan to fund our development and commercialization activities during the remainder of 2010 and beyond through the sale of equity securities as more fully described in the *Liquidity and Capital Resources* section in the following paragraphs.

Results of Operations*For the years ended June 30, 2010 versus June 30, 2009*

Sales and cost of goods sold for the year ended June 30, 2010 were both zero as compared to \$1,177,000 and \$501,000, respectively, for the comparable period in 2009. The decreases in sales of \$612,000 and cost of goods sold of \$501,000 were attributable to the discontinuance of sales of nutritional supplements effective April 1, 2009. Effective on that date, the Company licensed that technology and transferred all such customer relationships to a subsidiary of its former parent in consideration for a royalty on future sales. That transaction relieved the Company of the prospective expenses associated with the sales, customer relations, and administrative burden of managing that business, financing its operations, and maintaining the related intellectual property. The remaining decrease in sales of \$565,000 related to the conclusion of an advisory service project with FhCMB in connection with the pilot plant.

Research and development expense for the year ended June 30, 2010 was \$2,517,000 compared to \$847,000 for the comparable period in 2009. This increase of \$1,670,000, or 197%, was primarily due to: a) An increase of \$1,750,000 in services provided by FhCMB; b) A decrease of \$232,000 in personnel costs as those individuals became full-time employees of FhCMB in early fiscal 2009; c) An increase of \$96,000 in costs related to the hiring of a Chief Scientific Officer; and d) An increase of \$56,000 consisting primarily of expense related to the preparation of an Investigational New Drug application (IND) filing with the United States Food and Drug Administration.

General and administrative expense for the year ended June 30, 2010 was \$2,070,000 compared to \$1,755,000 for the comparable period in 2009. This increase of \$315,000, or 18%, was primarily due to increases of \$146,000 in financial advisory fees, \$121,000 in stock-based compensation, \$115,000 in investor relations expenses, \$100,000 in royalties, \$60,000 in patent related expenses, and \$53,000 in depreciation and amortization expenses offset by decreases of \$246,000 in legal expenses and \$34,000 in other expenses. Such changes are generally associated with the Company now being a stand-alone public entity for the entirety of year ended June 30, 2010 after the spin-off from its former parent during the prior year.

Other income (expense) for the year ended June 30, 2010 was an expense of \$1,488,000 compared to income of \$20,000 the comparable period in 2009. This change consisted of the following:

	2010	2009
Interest income	\$ 13,000	\$ 20,000
Interest expense	(13,000)	
Royalty income	27,000	
Change in the fair value of derivative instrument liability	(1,515,000)	
Total	\$ (1,488,000)	\$ 20,000

- a) Interest income decreased by \$7,000 reflecting the lower average balance of cash on hand during the comparable periods and lower interest rates.
- b) Interest expense increased by \$13,000 related to interest charges on balances due to FhCMB.
- c) The presence of royalty income in 2010 when there was no comparable amount in 2009 relates to an agreement with a subsidiary of the Company's former parent which commenced in April 2009 (see the discussion in the sales and cost of goods sold paragraph above).
- d) The \$1,515,000 expense related to the change in the fair value of derivative financial instruments is recorded in accordance with the guidance in ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity which became effective for the Company on July 1, 2009 and is further discussed in Note 6 to the financial statements.

The accounting guidance applicable to these warrants requires the Company (assuming all other inputs to the Black-Scholes model remain constant) to record a non-cash expense when the Company's stock price is rising and recording non-cash income when the Company's stock price is falling. The estimated fair value of this derivative liability increased from \$199,000 at July 1, 2009 to \$1,714,000 at June 30, 2010 primarily as a result of an increase in our stock price during that same period.

The calculation of this derivative liability is affected by factors which are subject to significant fluctuations and are not under our control. Consequently, this liability and, therefore, the resulting effect upon our net loss is subject to significant fluctuations and will continue to be subject to significant fluctuations until the warrants either expire in August 2013 or are exercised prior to that date.

Income tax expense for the years ended June 30, 2010 and 2009 reflects estimates for the minimum amounts of state income taxes due in states where we are required to file income tax returns. Our deferred tax assets resulting from our net operating losses are fully reserved in a valuation allowance account since it is more likely than not that such assets will not be realized.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations during fiscal 2009 and 2010 and have an accumulated deficit of \$13,519,000 as of June 30, 2010. Cash outflows for operating and investment activities during fiscal 2010 and 2009 totaled \$2,925,000 and \$3,642,000, respectively. The Company has historically financed its activities through the private placement of its equity securities. To date, the Company has dedicated most of its financial resources to research and development and general and administrative expenses as well as disbursements related to investments in intellectual property.

Edgar Filing: iBio, Inc. - Form 10-K

We had cash of \$910,000 at June 30, 2010 compared to \$1,039,000 at June 30, 2009. This decrease of \$129,000, or 12%, was due to the receipt of net proceeds of \$2,796,000 from the sale of common stock and warrants offset by net cash used of \$2,348,000 and \$577,000 related to operating activities and investing activities, respectively. We had a working capital deficiency of \$2,829,000 at June 30, 2010. Calculation of that amount includes the derivative instrument liability of \$1,714,000 at June 30, 2010 which does not require the disbursement of cash for extinguishment. Cash on-hand of \$283,000 as of October 8, 2010 is expected to support our activities through the balance of calendar 2010.

We have contractual obligations as of June 30, 2010 to FhCMB consisting of payments for services and minimum royalty amounts under our amended technology transfer and research agreements for the following periods:

Less than one year	\$ 3,200,000
One to three years	4,400,000
Four to five years	2,400,000
Six years or more	1,800,000
Total	\$ 11,800,000

The Less than one year amount includes \$1,100,000 due FhCMB which is recorded in Accounts Payable in our financial statements as of June 30, 2010.

We plan to fund our development and commercialization activities during the balance of 2010 and beyond through licensing arrangements and/or the sale of equity securities. We cannot be certain that such funding will be available on acceptable terms, or available at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. If we are unable to raise funds when required or on acceptable terms, we may have to: a) Significantly delay, scale back, or discontinue the development and/or commercialization of one or more product candidates; b) Seek collaborators for product candidates at an earlier stage than would otherwise be desirable and/or on terms that are less favorable than might otherwise be available; or c) Relinquish or otherwise dispose of rights to technologies, product candidates, or products that we would otherwise seek to develop or commercialize ourselves and cease operations.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of June 30, 2010 or 2009.

Capital Expenditures

The Company's capital expenditures, other than intellectual property, were not material during the years ended June 30, 2010 and 2009.

Critical Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (US GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On a continual basis, management reviews its estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such reviews, and if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates.

Our critical accounting policies are as follows:

Research and development;

Valuation and recoverability of intangible assets;

Stock-based compensation; and

Valuation of derivative instruments.

Research and Development. We expense research and development costs as incurred. Such costs include expenditures made to FhCMB for research and development services, fees paid to regulatory and scientific consultants, and salaries and related costs.

Intangible Assets. Intangible assets consist of intellectual property and patents. Amortization is being recorded on the straight-line basis over periods ranging from 10 years to 15 years based on contractual or estimated lives. The carrying value of intangible assets is evaluated whenever events or circumstances indicate that the carrying value may not be recoverable. Tests for impairment or recoverability require significant management judgment, and future events affecting cash flows and market conditions could result in impairment losses. During the fiscal years ended June 30, 2010 and 2009, no impairment losses were indicated or recorded.

Stock-Based Compensation. The Company accounts for stock-based compensation by estimating the fair value of such awards as of the date of grant utilizing the Black-Sholes option pricing model and then amortizing the fair value of each award over the applicable vesting period.

Derivative Instruments. The Company accounts for warrants issued in connection with the August 2008 financing as derivative instruments in accordance with certain US GAAP which

became effective July 1, 2009. Accordingly, the Company: a) estimated the fair value of such warrants as of July 1, 2009 and established a liability on the balance sheet through a reduction to Stockholders' Equity; and b) has recorded subsequent changes to that liability as of each subsequent balance sheet date as non-cash income or expense in the statement of operations for the related reporting period.

Recently Issued Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued the FASB Accounting Standards Codification (Codification or ASC) as the single source of authoritative US GAAP except for additional authoritative rules and interpretive releases issued by the SEC. The Codification is effective for financial statements issued for interim and annual periods ended after September 15, 2009. The Company adopted the Codification effective September 30, 2009 and such adoption did not have an impact upon the Company's financial statements.

Effective July 1, 2009, the Company adopted guidance in ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity . This guidance was effective for fiscal years beginning after December 15, 2008 and the adoption by the Company effective July 1, 2009 had a material impact upon the Company's financial statements. The provisions of this guidance and details concerning its adoption are discussed in Note 6 to the financial statements.

Impact of Inflation

The Company does not believe that inflation has significantly affected its results of operations.

Seasonality

Our operations are not impacted by seasonality.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our cash balances consist primarily of investments in money market savings accounts held at a major commercial bank. Deposit accounts at that institution are insured by the Federal Deposit Insurance Corporation for deposits up to \$250,000. As of June 30, 2010, the Company had uninsured cash balances totaling \$739,000.

Effective July 1, 2009, US GAAP required that the warrants issued by the Company in connection with the August 2008 financing be considered derivative instruments and that the Company report an estimated fair value of such warrants as a liability as of each balance sheet date and the change in that liability as non-cash income or expense in the statement of operations for the related reporting period.

The Company uses the Black-Scholes option pricing model to estimate its derivative instrument liability which requires several assumptions. This model is particularly sensitive to the estimated volatility in the price of the Company's common stock and the actual price of the Company's common stock as of each balance sheet date. An increase or decrease of 10% in either the

estimated volatility or the actual price of the Company's common stock as of June 30, 2010 would have had the effect of estimating a higher or lower value for such warrants, which would have resulted in a larger or smaller estimated derivative liability on the balance sheet, which would have resulted in a larger non-cash expense or benefit of approximately \$250,000 being recorded in the statement of operations.

Item 8. Financial Statements and Supplementary Data

For a list of financial statements and supplementary data filed as part of this report, see the Index to Financial Statements beginning at page F-1 of this Annual Report.

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

None.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing and as described in the following paragraphs, our chief executive officer and chief financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our independent registered public accounting firm, J.H. Cohn LLP (JHC), communicated to our audit committee on February 10, 2010 that a material weakness existed in our internal control over financial reporting. This weakness was comprised of financial accounting and disclosure deficiencies and financial reporting deficiencies for non-routine, complex transactions. This weakness resulted in additions and corrections to disclosures in our Form 10-Q prior to filing and in us not implementing the guidance in ASC 815-40, Derivative and Hedging Contracts in an Entity's Own Equity in a timely manner, which required the restatement of our financial statements as of and for the quarter ended September 30, 2009. Upon receipt of the communication from JHC, management took immediate action to prospectively remediate this weakness by establishing an in-depth independent internal review that did not previously exist.

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2010 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with US GAAP.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with US GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting is effective as of June 30, 2010.

This Annual Report on Form 10-K does not include attestation reports of our independent registered public accounting firms regarding internal control over financial reporting. Management's report thereon was not subject to attestation by our independent registered public accounting firms.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the Company's Proxy Statement for Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended June 30, 2010.

Item 11. Executive Compensation

Incorporated by reference from the Company's Proxy Statement for Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended June 30, 2010.

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

Incorporated by reference from the Company's Proxy Statement for Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended June 30, 2010.

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

Incorporated by reference from the Company's Proxy Statement for Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended June 30, 2010.

Item 14. Principal Accountant Fees and Services

Incorporated by reference from the Company's Proxy Statement for Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended June 30, 2010.

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 report is set forth in the index to financial statements at page 40 and is incorporated herein by reference
- (2) An index of exhibits incorporated by reference or filed with this Report is provided below

<u>Number</u>	<u>Description</u>
3.1	Form of Articles of Incorporation of iBioPharma, Inc. (3)
3.2	Form of Bylaws of iBioPharma, Inc. (3)
4.1	Form of Common Stock Certificate (3)
4.2	Form of Warrant to Purchase Common Stock of iBioPharma, Inc. for each Investor (5)
10.1	Separation and Distribution Agreement, dated as of November 14, 2007, between Integrated BioPharma, Inc. and the Registrant. (1)
10.2	Indemnification and Insurance Matters Agreement between Integrated BioPharma, Inc., and the Registrant (5)
10.3	Transitional Services Agreement between Integrated BioPharma, Inc. and the Registrant. (5)
10.4	Tax Allocation Agreement between Integrated BioPharma, Inc. and the Registrant. (5)
10.5	Form of Securities Purchase Agreement between various purchasers and the Registrant.
10.6	Technology Transfer Agreement, dated as of January 1, 2004, between the Registrant and Fraunhofer USA Center for Molecular Biotechnology, Inc. (3)
10.7	Non-Standard Navy Cooperative Research and Development Agreement, dated August 17, 2004, between the Registrant and Fraunhofer USA Center for Molecular Biotechnology, Inc. (2)
10.8	Supply License Agreement, dated as of March 22, 2006, between the Registrant and Mannatech, Inc. (2)
10.9	Form of Registration Rights Agreement with iBioPharma, Inc. for each Investor. (6)
10.10	Conversion Agreement, dated August 19, 2008, by and between iBioPharma, Inc. and Integrated BioPharma, Inc. (6)
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 (7).
31.2	Certification of Periodic Report by Chief Financial 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 (7).
32.1	Certification of Periodic Report by Chief Executive Officer Pursuant to 18 U.S.C.

- 44 -

Edgar Filing: iBio, Inc. - Form 10-K

Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (7).

32.2 Certification of Periodic Report by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (7).

- (1) Incorporated herein by reference to the Company's Form 10-12G filed with the Commission on March 7, 2008
- (2) Incorporated herein by reference to the Company's Form 10-12G filed with the Commission on June 18, 2008
- (3) Incorporated herein by reference to the Company's Form 10-12G filed with the Commission on July 11, 2008
- (4) Incorporated herein by reference to the Company's Form 10-12G filed with the Commission on July 17, 2008
- (5) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on August 12, 2008.
- (6) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on August 19, 2008.
- (7) Filed herewith.

- 45 -

Edgar Filing: iBio, Inc. - Form 10-K

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized on October 13, 2010.

iBio, Inc.
(Registrant)

By: /s/ Robert B. Kay

Robert B. Kay
Chief Executive Officer

In accordance with the Securities Exchange Act, this report has been signed below by the following persons on behalf of iBio, Inc. and in the capacities and on the dates indicated:

Signature	Title	Date
<u>/s/ Robert B. Kay</u> Robert B. Kay	Chief Executive Officer and Director (Principal Executive Officer)	October 13, 2010
<u>/s/ Pamela Bassett</u> Pamela Bassett, D.M.D.	Director	October 13, 2010
<u>/s/ Glenn Chang</u> Glenn Chang	Director	October 13, 2010
<u>/s/ James T. Hill</u> General James T. Hill (Ret.)	Director	October 13, 2010
<u>/s/ Frederick Larcombe</u> Frederick Larcombe	Chief Financial Officer (Principal Financial and Accounting Officer)	October 13, 2010
<u>/s/ John D. McKey</u> John D. McKey	Director	October 13, 2010
<u>/s/ Philip K. Russell</u> Philip K. Russell, M.D.	Director	October 13, 2010

Item 8: Financial Statements

IBIO, INC.
(Formerly iBioPharma, Inc.)

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Reports of Independent Registered Public Accounting Firms</u>	F - 2
<u>Balance Sheets as of June 30, 2010 and 2009</u>	F - 4
<u>Statements of Operations for the years ended June 30, 2010 and 2010</u>	F - 5
<u>Statement of Stockholders' Equity (Deficiency) for the years ended June 30, 2010 and 2009</u>	F - 6
<u>Statements of Cash Flows for the years ended June 30, 2010 and 2009</u>	F - 7
<u>Notes to Financial Statements</u>	F - 8
	F - 1

Edgar Filing: iBio, Inc. - Form 10-K

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
iBio, Inc.

We have audited the accompanying balance sheet of iBio, Inc. as of June 30, 2010, and the related statements of operations, stockholders' equity (deficiency) and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of iBio, Inc. as of June 30, 2010, and its results of operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 6 to the financial statements, effective July 1, 2009, the Company adopted guidance in Accounting Standards Codification 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred a net loss and negative cash flows from operating activities for the year ended June 30, 2010 and has an accumulated deficit and negative working capital as of June 30, 2010. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J. H. Cohn LLP

Eatontown, New Jersey
October 13, 2010

Edgar Filing: iBio, Inc. - Form 10-K

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
iBio, Inc.

We have audited the accompanying balance sheet of iBio, Inc. (formerly BioPharma, Inc.) as of June 30, 2009 and the related statements of operations, stockholders' equity (deficiency), and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of iBio, Inc. (formerly iBioPharma, Inc.) as of June 30, 2009, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey
September 28, 2009

iBio, Inc.
Balance Sheets

	June 30, 2010	June 30, 2009
Assets		
Current assets:		
Cash	\$ 909,932	\$ 1,039,244
Accounts receivable	47,460	209,795
Prepaid expenses and other current assets	68,150	16,569
 Total current assets	 1,025,542	 1,265,608
Fixed assets, net	11,050	14,878
Intangible assets, net	3,893,653	3,649,878
 Total assets	 \$ 4,930,245	 \$ 4,930,364
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,007,166	\$ 112,331
Accrued expenses	132,865	429,809
Derivative instrument liability (see Note 6)	1,714,084	
 Total liabilities	 3,854,115	 542,140
Commitments and contingencies		
Stockholders equity:		
Preferred stock, no par value, 5,000,000 shares authorized, no shares outstanding		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 28,272,655 and 23,357,519 issued and outstanding as of June 30, 2010 and 2009, respectively	28,273	23,358
Additional paid-in capital	14,567,349	13,049,734
Accumulated deficit	(13,519,492)	(8,684,868)
 Total stockholders equity	 1,076,130	 4,388,224
 Total liabilities and stockholders equity	 \$ 4,930,245	 \$ 4,930,364

The accompanying notes are an integral part of these
financial statements

iBio, Inc.
Statements of Operations

	Years ended June 30,	
	2010	2009
Sales	\$	\$ 1,176,604
Cost of goods sold		500,835
Gross profit		675,769
Operating expenses:		
Research and development	2,517,360	797,400
General and administrative	2,069,979	1,804,561
Total operating expenses	4,587,339	2,601,961
Operating loss	(4,587,339)	(1,926,192)
Other income (expense):		
Interest income	12,731	20,424
Interest expense	(13,109)	
Royalty income	26,792	
Change in the fair value of derivative instrument liability (see Note 6)	(1,514,695)	
Other income (expense)	(1,488,281)	20,424
Loss before income taxes	(6,075,620)	(1,905,768)
Income tax expense	2,400	1,528
Net loss	\$ (6,078,020)	\$ (1,907,296)
Net loss per common share - Basic and diluted	\$ (0.22)	\$ (0.09)
Weighted average common shares outstanding - Basic and diluted	27,303,094	20,265,667

The accompanying notes are an integral part of these
financial statements

iBio, Inc.
Statement of Stockholders' Equity (Deficiency)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, July 1, 2008		\$	100	\$ 575,000	\$	\$ (6,777,572)	\$ (6,202,572)
Shares cancelled			(100)	(575,000)	575,000		
Shares issued to shareholders of Former parent, Integrated BioPharma, Inc.			19,845,061	19,845	(19,845)		
Shares forfeited by shareholder of Former parent, Integrated BioPharma, Inc.			(100,000)	(100)	100		
Shares issued in connection with conversion of intercompany debt with Integrated BioPharma, Inc.			1,266,706	1,267	7,908,227		7,909,494
Issuance of common stock and warrants for cash at \$2.13 per unit, net of expenses			2,345,752	2,346	4,577,956		4,580,302
Stock-based compensation					8,296		8,296
Net loss						(1,907,296)	(1,907,296)
Balance, June 30, 2009			23,357,519	23,358	13,049,734	(8,684,868)	4,388,224
Cumulative effect of a change in accounting principle - Adoption of ASC 815-40 (see Note 6)					(1,442,785)	1,243,396	(199,389)
Issuance of common stock and warrants for cash at \$0.65 per unit, net of expenses			4,615,385	4,615	2,791,272		2,795,887
Issuance of common stock in accordance with anti-dilution provisions of the August 2008 financing			299,751	300	(300)		
Stock-based compensation expense					143,828		143,828
Issuance of warrants to consultant					25,600		25,600
Net loss						(6,078,020)	(6,078,020)
Balance, June 30, 2010		\$	28,272,655	\$ 28,273	\$ 14,567,349	\$ (13,519,492)	\$ 1,076,130

The accompanying notes are an integral part of these
financial statements

iBio, Inc.
Statements of Cash Flows

	Years ended June 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (6,078,020)	\$ (1,907,296)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in the fair value of derivative instrument liability (see Note 6)	1,514,695	
Depreciation and amortization	337,029	283,952
Stock-based compensation	143,828	13,059
Issuance of warrants for services	25,600	
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	162,335	(104,395)
(Increase) decrease in prepaid expenses and other current assets	(51,581)	27,106
Increase (decrease) in accounts payable	1,894,835	(393,587)
Increase (decrease) in accrued expenses	(296,944)	56,354
Net cash used in operating activities	(2,348,223)	(2,024,807)
Cash flows from investing activities:		
Additions to intangible assets	(576,976)	(562,759)
Payment under terms of agreement to purchase intellectual property		(1,050,000)
Purchase of fixed assets		(4,580)
Net cash used in investing activities	(576,976)	(1,617,339)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants, net of expenses	2,795,887	4,580,302
Advances from former parent		82,083
Net cash provided by financing activities	2,795,887	4,662,385
Net increase (decrease) in cash	(129,312)	1,020,239
Cash - Beginning of year	1,039,244	19,005
Cash - End of year	\$ 909,932	\$ 1,039,244
Supplemental disclosures of cash flow information:		
Cash paid for:		
Interest	\$	\$ 898
Income taxes	\$ 2,120	\$ 1,478

Edgar Filing: iBio, Inc. - Form 10-K

Supplemental disclosures of non-cash operating,
investing, and financing activities:

Cumulative effect of a change in accounting principle - Adoption of ASC 815-40 (see Note 6)	\$	199,389	\$
Issuance of common stock in accordance with anti-dilution provisions of the August 2008 financing	\$	300	\$
Cancellation of common stock owned by former parent	\$		\$ 575,000
Issuance of common stock to stockholders of former parent	\$		\$ 19,845
Issuance of common stock upon conversion of intercompany debt due to former parent	\$		\$ 7,909,494

The accompanying notes are an integral part of these
financial statements

F - 7

iBio, Inc.
Notes to Financial Statements

1) Business

iBio, Inc. (iBio or the Company) is a biotechnology company focused on commercializing its proprietary technology, the iBioLaunch platform, for the production of biologics including vaccines and therapeutic proteins. Our strategy is to utilize our technology for development and manufacture of our own product candidates and to work with both corporate and government clients to reduce their costs during product development and meet their needs for low cost, high quality biologics manufacturing systems. Our near-term focus is to establish business arrangements for use of our technology by licensees for the development and production of products for both therapeutic and vaccine uses. Vaccine candidates presently being advanced on our proprietary platform are applicable to newly emerging strains of H1N1 swine-like influenza and H5N1 for avian influenza.

Prior to April 1, 2009, the Company also used plants as a source of novel, high quality nutritional supplements and sold those products to customers located primarily in the United States. Effective that date, the Company licensed that process and transferred all such customer relationships to a subsidiary of its Former Parent (as defined below) in consideration for a royalty on future net sales.

The Company was formerly known as InB:Biotechnologies, Inc. and was a wholly owned subsidiary of Integrated BioPharma, Inc. (Integrated or Former Parent). Effective August 18, 2008, the Company was spun-off from Integrated in the form of a dividend to Integrated stockholders. Immediately following the spin-off, the Company became a public company known as iBioPharma, Inc. with stock traded on the OTC Bulletin Board under the symbol IBPM. Effective August 10, 2009, the Company changed its name to iBio, Inc. See Note 9 for additional information in connection with these transactions.

The Company is operating in one business segment for both years presented.

2) Liquidity and Basis of Presentation

The Company incurred significant losses and negative cash flows from operations during fiscal 2010 and 2009 and has an accumulated deficit of \$13,519,000 and a working capital deficit of \$2,829,000 as of June 30, 2010. Cash outflows for operating and investment activities during fiscal 2010 and 2009 totaled \$2,925,000 and \$3,642,000, respectively. The Company has historically financed its activities through the private placement of its equity securities. To date, the Company has dedicated most of its financial resources to research and development and general and administrative expenses as well as disbursements related to investments in intellectual property. Cash on hand as of June 30, 2010 is expected to support the Company's activities through the balance of calendar 2010.

The Company plans to fund our development and commercialization activities during the balance of 2010 and beyond through licensing arrangements and/or the sale of equity securities. The Company cannot be certain that such funding will be available on acceptable 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 the Company is unable to raise funds when required or on acceptable terms, it may have to: a) Significantly delay, scale back, or discontinue the development and/or commercialization of one or more product candidates; b) Seek collaborators for product candidates at an earlier stage than would otherwise be desirable and/or on terms that are less favorable than might otherwise be available; or c) Relinquish or otherwise dispose of rights to technologies, product candidates, or products that it would otherwise seek to develop or commercialize itself and possibly cease operations.

These matters raise substantial doubt about the Company's ability to continue as a going concern. These financial statements were prepared under the assumption that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of that uncertainty.

3) Accounting Policies

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The areas most significantly affected by estimates consist of:

Valuation and recoverability of intangible assets;

Stock-based compensation;

Valuation of derivative instruments; and

Income taxes and valuation allowance on deferred income taxes.

On a regular basis, management reviews its estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such reviews, and if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates.

Revenue Recognition. The Company recognizes revenue when persuasive evidence that an arrangement exists with a customer or client, the price to the purchaser is fixed or determinable, the product has been shipped or the service has been performed, the Company has no significant remaining obligation, and collectability is reasonably assured.

Edgar Filing: iBio, Inc. - Form 10-K

Research and Development. The Company expenses research and development costs as incurred.

Stock-Based Compensation. The Company accounts for options granted to employees by measuring the cost of services received in exchange for the award of equity instruments based upon the fair value of the award on the date of grant. The fair value of that award is then ratably recognized as expense over the period during which the recipient is required to provide services in exchange for that award. Options and warrants granted to consultants and other non-employees are valued as of the grant date and subsequently adjusted to fair value at the end of each reporting period until such options and warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period.

Income Taxes. The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. 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 recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain.

Earnings (Loss) Per Share. The Company calculates basic net loss per common share by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share since the inclusion of common shares issuable pursuant to the exercise of stock option agreements and warrants in the calculation of diluted net loss per common share would have been anti-dilutive.

The following table summarizes the number of common shares excluded from the calculation of diluted net loss per common share for years ended June 30, 2010 and 2009:

	2010	2009
Warrants	3,085,811	2,345,752
Stock options	2,210,000	780,000
Total	5,295,811	3,125,752

Financial Instruments. The Company records financial instruments consisting of cash, accounts receivable, and accounts payable at their historical cost and considers such amounts to approximate fair value due to their short term nature of those instruments. Financial instruments consisting of certain of the Company's warrants are required to be accounted for as derivative liabilities and are recorded at fair value as discussed in Note 6.

Intangible Assets. The Company accounts for intangible assets at their historical cost and records amortization utilizing the straight-line method over periods ranging from 10 years to 15 years based upon their estimated useful lives. The Company reviews them for impairment whenever events or changes in business circumstances indicate that the carrying amount of such assets may not be fully recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flow expected to be derived from the use of those assets is less than their carrying values. During the years ended June 30, 2010 and 2009, no impairment losses were recorded.

Contingent Liabilities. The Company records liabilities when it is probable a liability has been incurred and the amount can be reasonably estimated or determined. As of June 30, 2010 and 2009, there were no accruals for contingent liabilities.

4) Recently Issued Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued the FASB Accounting Standards Codification (Codification or ASC) as the single source of authoritative U.S. generally accepted accounting principles except for additional authoritative rules and interpretive releases issued by the SEC. The Codification is effective for financial statements issued for interim and annual periods ended after September 15, 2009. The Company adopted the Codification effective September 30, 2009 and such adoption did not have an impact upon the Company s financial statements.

Effective July 1, 2009, the Company adopted guidance in ASC 815-40, Derivatives and Hedging - Contracts in Entity s Own Equity . This guidance was effective for fiscal years beginning after December 15, 2008 and the adoption by the Company effective July 1, 2009 had a material impact upon the Company s financial statements. The provisions of this guidance and details concerning its adoption are discussed in Note 6.

5) Intangible Assets

Intangible assets as of June 30, 2010 and 2009 consist of the following:

	2010	2009
Intellectual property	\$ 3,600,000	\$ 3,600,000
Patents	1,760,548	1,183,572
	5,360,548	4,783,572
Accumulated amortization	(1,466,895)	(1,133,694)
Net	\$ 3,893,653	\$ 3,649,878

Intellectual property consists of technology for producing targeted proteins in plants for the development and manufacture of novel vaccines and therapeutics for humans and certain veterinary applications (the Technology). The Company acquired this Technology from the Center for Molecular Biotechnology of Fraunhofer USA, Inc. (FhCMB) through a Technology Transfer Agreement (the TTA) dated December 18, 2003, as amended, for \$3,600,000 which

Edgar Filing: iBio, Inc. - Form 10-K

was paid through a series of installment payments. The final installments totaling \$1,050,000 were paid during the year ended June 30, 2009.

Terms of the TTA require FhCMB to provide the Company with research and development services related to the commercialization of the Technology and allows FhCMB to apply the Technology to the development and production of certain vaccines for use in developing countries. The most recent amendment to the TTA requires: a) the Company to make payments to FhCMB of \$2,000,000 per year for five years, aggregating \$10,000,000, for such services beginning in November 2009; and b) FhCMB to expend at least equal amounts during the same timeframe for research and development services related to the commercialization of the Technology. Additionally, under the terms of the TTA and for a period of fifteen years: a) the Company shall pay FhCMB 1% of all receipts derived by the Company from sales of products produced utilizing the Technology and 15% of all receipts derived by the Company from licensing the Technology to third parties with an overall minimum annual payment of \$200,000 beginning with the twelve months ending December 31, 2010; and b) FhCMB shall pay the Company 9% of all receipts from sales, licensing, or commercialization of the Technology in developing countries as described above.

The Company made payments of \$1,100,000 and \$1,050,000 during the fiscal years ended June 30, 2010 and 2009, respectively, in compliance with the terms of the TTA. The Company's remaining commitment of \$1,000,000 as of June 30, 2010 is included in Accounts Payable.

Patents consists of payments for services and fees related to the further development and protection of the Company's patent portfolio.

Amortization expense for intangible assets is recorded utilizing the straight-line method over periods ranging from ten to fifteen years, is included in selling and administrative expenses, and totaled \$333,201 and \$280,142, during the years ended June 30, 2010 and 2009, respectively.

The estimated annual amortization expense for intangible assets for the five succeeding fiscal years and thereafter is as follows as of June 30, 2010:

Fiscal year ending June 30,	
2011	\$ 362,000
2012	362,000
2013	362,000
2014	362,000
2015	362,000
Thereafter	2,084,000
	\$ 3,894,000

6) Derivative Financial Instruments

Introduction

Effective July 1, 2009, accounting principles generally accepted in the United States of America required that the warrants issued by the Company in connection with the August 2008 financing and previously recorded as a component of equity, must now be reported as a liability at fair value as of each balance sheet date and the change in that liability be reported as non-cash income or expense in the statement of operations for the related reporting period.

The Company uses the Black-Scholes option pricing model to estimate its derivative instrument liability which requires several assumptions, including the current price of the Company's common stock. This model is particularly sensitive to the assumed volatility in the price of the Company's common stock and the actual price of the Company's common stock as of each balance sheet date. Increases in the assumed volatility or the actual price of the Company's common stock has the effect of estimating a higher value for such warrants, which results in a larger estimated derivative liability on the balance sheet, which results in a larger non-cash expense being recorded in the statement of operations.

Thus, for example, the accounting guidance applicable to these warrants requires that the Company (assuming all other inputs to the Black-Scholes model remain constant) record non-cash expense when the Company's stock price is rising and record non-cash income when the Company's stock price is falling.

Detail Discussion

Effective July 1, 2009, the Company adopted guidance in ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity. The applicable provisions of this guidance require that:

- a) Warrants issued by the Company in the August 2008 financing transaction containing cashless exercise and downside ratchet provisions were previously accounted for as equity instruments in accordance with accounting principles generally accepted in the United States of America in effect through June 30, 2009 must now be considered and accounted for as derivative instruments effective July 1, 2009 and the related estimated fair value reported as a liability as of each balance sheet date; and
- b) Such derivative instruments must be marked-to-market as of each balance sheet date and the change in the reported estimated fair value of such instruments be recorded as non-cash income or expense in the statement of operations.

In accordance with this guidance, the Company estimated the fair value of these instruments to be \$199,389 as of July 1, 2009 and established a derivative instrument liability in that amount by recording reductions of \$1,442,785 in additional paid-in capital and \$1,243,396 in accumulated deficit. The effect of this adjustment is presented as a cumulative effect of change in an accounting principle in the statement of stockholders equity (deficit).

Edgar Filing: iBio, Inc. - Form 10-K

As of June 30, 2010, the estimated fair value of this derivative liability was \$1,714,084 and the resulting increase of \$1,514,695 during the year ended June 30, 2010 was reported as non-cash expense in our statement of operations as a component of other income (expense).

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of these derivative instruments. The Company considers them to be Level 2 type instruments in accordance with ASC 820-10 Fair Value Measurements and Disclosures as the inputs used to estimate their value are observable either directly or indirectly. The Company's common stock price input was based upon the closing market price for the date indicated. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the remaining contractual term of the instruments. The expected volatility assumptions were based upon the historical volatility of the stock of comparable companies due to the Company limited trading history. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected term assumptions were based upon the remaining contractual term of these instruments.

The inputs and assumptions made in calculating the fair value of these derivative instruments as of June 30, 2010 and July 1, 2009 were as follows:

	2010	2009
Common stock price	\$ 1.38	\$ 0.45
Risk free interest rate	1.04%	1.95%
Dividend yield	0%	0%
Volatility	98%	80%
Remaining contract term (in years)	3.2	4.2

7) Income Taxes

The components of the Company's deferred tax assets as of June 30, 2010 and 2009 are as follows:

	2010	2009
Deferred tax assets:		
Net operating loss	\$ 3,792,000	\$ 2,578,000
Accounts payable amounts not currently deductible	539,000	
Stock-based compensation	57,000	
Vacation accrual	13,000	
Valuation allowance	(4,401,000)	(2,578,000)
Total		
Less current portion		
Net long-term deferred tax asset	\$	\$

Edgar Filing: iBio, Inc. - Form 10-K

Prior to the spin-off from its Former Parent in August 2008 as described in Note 9, the Company was included in the Former Parent's combined Federal income tax filings. Under the terms of the spin-off, the Company is entitled to receive in cash a portion of any future reduction in taxes realized in the Former Parent's combined Federal income tax filings through the use of net operating losses generated by the Company prior to the spin-off.

Federal net operating losses of approximately \$1.5 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.

Federal and state net operating losses of approximately \$9.3 million and \$10.8 million are available to the Company as of June 30, 2010 and will expire at various dates through 2030. These carryforwards could be subject to certain limitations in the event there is a change in control of the Company and have been fully reserved in the Company's valuation allowance account as there is substantial doubt the Company or the Former Parent would be able to use these net operating losses to offset future taxable income before the net operating losses expire and the Company or the Former Parent is able to realize the related benefit.

The components of the provision for income taxes for the years ended June 30, 2010 and 2009 consists of the following:

	2010	2009
Current - State	\$ 2,400	\$ 1,528
Deferred - Federal	(1,552,000)	(648,000)
Deferred - State	(271,000)	(113,000)
 Total	 (1,820,600)	 (759,472)
Change in valuation allowance	1,823,000	761,000
 Income tax expense	 \$ 2,400	 \$ 1,528

A reconciliation of the statutory tax rate to the effective tax rate for the years ended June 30, 2010 and 2009 is as follows:

	2010	2009
Statutory Federal income tax rate	34%	34%
State (net of Federal benefit)	5%	6%
Non-deductible expenses - Change in fair value of derivative financial instruments	(9%)	0%
Change in valuation allowance	(30%)	(40%)
 Effective income tax rate	 0%	 0%

Edgar Filing: iBio, Inc. - Form 10-K

Federal and state tax returns for the year ended June 30, 2006 and prior are no longer subject to examination by Federal and state tax authorities. However, the net operating losses derived during such periods continue to be subject to Federal and state examination until the statute of limitations closes on any year in which a net operating loss is utilized.

The Company adopted ASC Topic 740 which clarifies the accounting for uncertainty in income taxes recognized in the financial statements. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. There were no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return that have been recorded in the Company's financial statements as of or for the years ended June 30, 2010 and 2009.

Additionally, ASC Topic 740 provides guidance on the recognition of interest and penalties related to income taxes. The Company's policy is to record interest in other income/expense and penalties in general and administrative expense. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the years ended June 30, 2010 and 2009.

8) Commitments and Contingencies

a) Leases

The Company leases administrative office space in Newark, Delaware from FhCMB on a month-to-month basis. Total rent expense was \$13,512 for each of the years ended June 30, 2010 and 2009.

b) Research and Royalty Agreements

As previously described in Note 5, the Company acquired Technology from FhCMB through a TTA dated December 18, 2003, as amended.

Terms of the TTA require the Company to: a) make payments to FhCMB of \$2,000,000 per year for five years, aggregating \$10,000,000, for research and development services beginning in November 2009; and b) pay FhCMB 1% of all receipts derived by the Company from sales of products produced utilizing the Technology and 15% of all receipts derived by the Company from licensing the Technology to third parties with an overall minimum annual payment of \$200,000 beginning with the twelve months ending December 31, 2010.

Remaining minimum commitments under the terms of the TTA as of June 30, 2010 are as follows:

Less than one year	\$ 3,200,000
Two to three years	4,400,000
Four to five years	2,400,000
Six years or more	1,800,000
Total	\$ 11,800,000

The Less than one year amount includes \$1,100,000 due to FhCMB under the terms of the TTA which is recorded in Accounts Payable as of June 30, 2010.

c) Resolution of Contingency

The Company previously reported a disagreement with FhCMB as of June 30, 2009 regarding whether a certain technical milestone was achieved by FhCMB under a vaccine research study which would trigger the obligation of a \$250,000 payment by the Company to FhCMB. In connection with the resolution of that disagreement during the year ended June 30, 2010, the Company recorded \$250,000 in research and development expenses and an accrued liability in the same amount. That amount is included in Accounts Payable as of June 30, 2010.

9) Equity Transactions

a) Spin-Off From Former Parent

In November 2007, the Company entered into a Separation and Distribution Agreement (the Distribution) with its Former Parent, whereby the Former Parent agreed to distribute, pro rata, to the holders of its common stock, all of the shares it owned of the Company s common stock. The Distribution was completed on August 18, 2008 through:

a) The cancellation of 100 common shares with no par value and an assigned value of \$575,000; and

b) The issuance of 19,845,061 common shares with a par value of \$0.001 with an assigned value of \$19,845.

Each shareholder of the Former Parent received one share of the Company for each share the shareholder owned as of August 12, 2008, the Record Date. The Distribution qualified as a tax-free reorganization under Section 355 of the Internal Revenue Code of 1986, as amended. The Agreement prohibits the Company from issuing additional shares of its common stock in excess of the shares issued with respect to the Distribution for the two years immediately following the effective date of the Distribution. Subsequent to this transaction, one shareholder of the Former Parent forfeited 100,000 shares in connection with the rescission of a consulting agreement and returned them to the Company and they were cancelled.

b) Conversion of Intercompany Debt

Concurrent with the effective date of the spin-off transaction described above, the Former Parent entered into a Conversion Agreement, whereby the Former Parent caused intercompany debt aggregating \$7,909,494 to be used as follows:

i) \$2,700,000 for the purchase of 1,266,706 shares of the Company, representing 6% of the then outstanding shares of the Company; and

ii) \$5,209,494 to be contributed to additional paid-in capital.

Edgar Filing: iBio, Inc. - Form 10-K

Subsequent to the private placements as discussed below, the Former Parent owned 4.5% and 5.4% of the Company as of June 30, 2010 and 2009, respectively.

c) Private Placement - August 2008

Concurrent with the effective date of the spin-off transaction described above, the Company issued 2,345,752 shares of common stock at \$2.13 per share and received net proceeds of \$4,577,956. The Company also issued warrants for the purchase of: a) 1,172,876 shares of common stock with an exercise price of \$3.20 per share; and b) 1,172,876 shares of common stock with an exercise price of \$4.26 per share. The number of warrant shares and the exercise prices are subject to adjustment through August 18, 2011 should the Company issue common stock at a price per share less than \$2.13. The warrants were immediately exercisable and expire August 18, 2013.

Proceeds from the issuance of these instruments were allocated to common stock and warrants based upon the relative amounts of the value of the common shares and the estimated fair value of the warrants. The warrants were considered a component of equity and the amount of net proceeds allocated to them were accounted for as an addition to additional paid-in capital. Effective July 1, 2009, accounting principles generally accepted in the United States of America required that the Company report the estimated fair value of such warrants as a liability as of each balance sheet date and the change in that liability as non-cash income or expense in the statement of operations for the related reporting period. The accounting for these warrants is described in Note 6.

Effective on September 10, 2009 with the September 2009 private placement described immediately below, the number of warrant shares and the exercise prices were adjusted in accordance with the terms of the August 2008 private placement.

d) Private Placement - September 2009

On September 10, 2009, the Company issued 4,615,385 shares of common stock at \$0.65 per unit and received net proceeds of \$2,795,887 and issued warrants to the placement agent for the purchase of 250,587 shares of common stock at a price of \$0.65 per share. The warrants were 100% vested upon issuance and expire on September 10, 2014. The Company estimated the fair value of the warrants to be \$92,637

Additionally, in connection with the September 2009 financing, the Company:

- i) Issued 299,751 shares of common stock to the investors in the August 2008 financing in accordance with the anti-dilution provisions of that offering. The Company accounted for the issuances of those shares as a reduction of additional paid-in capital and an increase in common stock at the aggregate par value of \$300; and

- ii) Adjusted the warrant agreements with the investors in the August 2008 financing to provide for the purchase of an additional 369,472 shares of common stock and adjusted the exercise prices as follows:
- 1) Warrants for the purchase of 1,172,876 at \$3.20 per common share were revised to provide for the purchase of 1,350,073 at \$2.78 per common share; and
 - 2) Warrants for the purchase of 1,172,876 at \$4.26 per common share were revised to provide for the purchase of 1,365,151 at \$3.66 per common share.

The accounting for these warrants issued in connection with the August 2008 financing is described in Note 6.

10) Share Based Payments

The Company accounts for options granted to employees by measuring the cost of services received in exchange for the award of equity instruments based upon the fair value of the award on the date of grant. The fair value of that award is then ratably recognized as expense over the period during which the recipient is required to provide services in exchange for that award. Options and warrants granted to consultants and other non-employees are valued as of the grant date and subsequently adjusted to fair value at the end of each reporting period until such options and warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period.

a) Stock Options

On August 12, 2008, the Company adopted the iBioPharma 2008 Omnibus Equity Incentive Plan (the Plan) for employee, officers, directors, or external service providers. Under the provisions of the Plan, the Company may grant options to purchase stock and/or make awards of restricted stock up to an aggregate amount of 10,000,000 shares. Options granted under the Plan may be either incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the Code), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. Options granted under the Plan vest ratably at the end of each twelve month period within either a three or five year period from the date of grant.

Share based compensation expense for the years ended June 30, 2010 and 2009 was recorded in the statements of operations as follows:

	2010	2009
Research and development	\$ 9,768	\$
General and administrative	134,060	13,059
Total	\$ 143,828	\$ 13,059

Edgar Filing: iBio, Inc. - Form 10-K

For the fiscal year ended June 30, 2009, share based compensation expense of \$13,059 recorded in general and administrative expenses included \$4,763 allocated from our Former Parent for our employees and directors who received compensation in the form of stock options for the purchase of our Former Parent's stock.

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of such instruments. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected volatility assumption was based upon the historical volatility of the common stock of comparable companies due to the Company's limited trading history. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected term assumption for employee options was determined utilizing the simplified method provided in Staff Accounting Bulletin No. 107, *Share-Based Payment*, which averages an award's vesting period with its contractual term. The expected term assumption for vendors' options and warrants was determined using the contractual term of each award. No forfeitures have been assumed due to the limited operating history of the Company and the small number of parties who have received awards.

Assumptions made in calculating the fair value of options and warrants issued during the years ended June 30, 2010 and 2009 were as follows:

	2010	2009
Risk-free interest rate	0.3% to 3.4%	1.7%
Dividend yield	0%	0%
Expected volatility	80% to 98%	80%
Expected term (in years)	1.4 to 10.0	4.3

The expected term information for fiscal 2010 includes options issued to FhCMB for the purchase of 100,000 shares of common stock with a contractual term of ten years. Otherwise, it would range from 1.4 to 6.5 years.

On August 10, 2009, the Company granted options to members of management for the purchase of 500,000 shares of common stock at a price of \$0.66 per share. The options vest ratably on the first through fifth anniversary dates of the grant and expire on August 10, 2019. The Company estimated the fair value of the options on the grant date to be \$216,000 and is recording such expense ratably over the vesting period within general and administrative expenses.

On August 10, 2009, the Company granted options to members of the Board of Directors for the purchase of 180,000 shares of common stock at a price of \$0.66 per share. The options vest ratably on the first, second, and third anniversary dates of the grant and expire on August 10, 2019. The Company estimated the fair value of the options on the grant date to be \$77,760 and is recording such expense ratably over the vesting period within general and administrative expenses.

Edgar Filing: iBio, Inc. - Form 10-K

On February 25, 2010, the Company granted options to an employee for the purchase of 30,000 shares of common stock at a price of \$0.87 per share. The options vest ratably on the first, second, and third anniversary dates of the grant and expire on February 25, 2020. The Company estimated the fair value of the options on the grant date to be \$18,750 and is recording such expense ratably over the vesting period within general and administrative expenses.

On March 1, 2010, the Company granted options to a member of the Board of Directors for the purchase of 60,000 shares of common stock at a price of \$0.87 per share. The options vest ratably on the first, second, and third anniversary dates of the grant and expire on February 25, 2020. The Company estimated the fair value of the options on the grant date to be \$45,840 and is recording such expense ratably over the vesting period within general and administrative expenses.

On March 1, 2010, the Company granted options to an employee for the purchase of 500,000 shares of common stock at a price of \$0.87 per share. The options vest ratably on January 1, 2011 and the four subsequent anniversary dates, and expire on February 25, 2020. The Company estimated the fair value of the options on the grant date to be \$391,000 and is recording such expense ratably over the vesting period within research and development expense. This employee serves as the Company's Chief Scientific Officer and simultaneously serves as Executive Director of FhCMB which performs research and development activities on behalf of the Company as further described in Note 8.

On March 1, 2010, the Company granted options to FhCMB for the purchase of 100,000 shares of common stock at a price of \$0.87 per share. The options vest ratably on the first through third anniversary dates of the grant provided FhCMB's Executive Director serves as the Company's Chief Scientific Officer throughout the vesting period and expire on February 25, 2020. The Company estimates the fair value of these options at each reporting period and is recording such expense, as adjusted, over the vesting period within research and development expense. During the year ended June 30, 2010, the Company recorded \$9,767 in expense related to these options.

On April 1, 2010, the Company granted options to a member of the Board of Directors for the purchase of 60,000 shares of common stock at a price of \$1.05 per share. The options vest ratably on the first, second, and third anniversary dates of the grant and expire on February 28, 2020. The Company estimated the fair value of the options on the grant date to be \$43,980 and is recording such expense ratably over the vesting period within general and administrative expenses.

Edgar Filing: iBio, Inc. - Form 10-K

A summary of the changes in options outstanding during the years ended June 30, 2010 and 2009 is as follows:

	Number of Shares	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at August 12, 2008, inception of the Plan					
Granted	780,000	\$0.21-\$0.31	\$ 0.21		
Exercised					
Terminated					
Outstanding at June 30, 2009	780,000	\$0.21-\$0.31	\$ 0.21		
Granted	1,430,000	\$0.66-\$1.05	\$ 0.78		
Exercised					
Terminated					
Outstanding and expected to vest at June 30, 2010	2,210,000	\$0.20-\$1.05	\$ 0.58	9.1	\$ 1,770,700
Options exercisable at June 30, 2010	193,240	\$0.20-\$0.31	\$ 0.22	8.7	\$ 909,400

The weighted average fair value of options granted during the years ended June 30, 2010 and 2009 was \$0.64 and \$0.13, respectively.

The unrecognized share-based compensation cost related to non-vested options as of June 30, 2010 was \$998,703 as measured utilizing the value as of the date of grant. These costs are expected to be recognized over a weighted-average period of approximately 3.8 years. The total fair value of shares vested during the years ended June 30, 2010 and 2009 as measured utilizing the value as of the date of grant was \$29,807 and zero, respectively.

b) Warrants

On July 13, 2009, the Company issued warrants to a third party for the purchase of 100,000 shares of common stock at a price of \$0.35 per share in connection with a professional service agreement. The warrants were 100% vested upon issuance and expire on July 13, 2014. The Company estimated the fair value of the warrants to be \$25,600 and accounted for them as an expense within general and administrative expenses on the date of issuance with a corresponding increase to additional paid-in capital.

In connection with the financing transaction on September 10, 2009, the Company issued warrants to the placement agent for the purchase of 250,587 shares of common stock at a price of \$0.65 per share and adjusted the warrant agreements issued to the investors in the August 2008 financing to provide for the purchase of an additional 369,472 shares of common stock ranging from \$2.78 to \$3.66. See Note 9(d)(ii) for a detailed discussion of such issuances and adjustments.

On November 15, 2009, the Company issued warrants to a third party for the purchase of 20,000 shares of common stock at a price of \$1.00 per share in connection with a professional service agreement. The warrants vest in equal amounts on the six and twelve months anniversaries after the date of issuance and expire on November 15, 2011. In accordance with applicable accounting

Edgar Filing: iBio, Inc. - Form 10-K

guidance, the Company records the estimated fair value of such warrants as a liability as of each balance sheet date until such warrants are vested. Until that date, the change in that liability is recorded in the statement of operations for the related reporting period. During the year ended June 30, 2010, the Company recorded \$13,720 in expense related to these warrants within general and administrative expenses.

A summary of the changes in warrants outstanding during the years ended June 30, 2010 and 2009 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at July 1, 2008	2,345,752	\$ 3.73		
Granted				
Exercised				
Terminated				
Outstanding at June 30, 2009	2,345,752	\$ 3.73		
Granted	740,059	\$ 1.91		
Exercised				
Terminated				
Outstanding at June 30, 2010	3,085,811	\$ 2.88	3.2	\$ 293,529
Exercisable at June 30, 2010	3,065,811	\$ 2.88	3.3	\$ 289,729

11) Significant Risks and Uncertainties and Related Party Transactions

a) Concentrations of Credit Risk-Cash

The Company maintains balances at a commercial financial institution. Deposit accounts at the institution are insured by the Federal Deposit Insurance Corporation for deposits up to \$250,000. As of June 30, 2010, the Company had uninsured cash balances totaling \$739,000.

b) Concentrations of Credit Risk-Receivables

The Company routinely assesses the financial strength of its customers and, based upon factors surrounding the credit risk of its customers, establishes an allowance for uncollectible accounts and, as a consequence, believes that its accounts receivable credit risk exposure beyond such allowances is limited. The Company does not require collateral in relation to its trade accounts receivable credit risk. There were no allowances for uncollectible accounts or bad debt expenses as of or for the years ended June 30, 2010 and 2009.

c) Major Customers

As previously indicated in Note 1, through April 1, 2009, the Company sold plant-based, high quality nutritional supplements. Effective on that date, the Company licensed that process and transferred all such customer relationships to a subsidiary of its Former Parent in consideration for a royalty on net sales.

Sales of nutritional supplements for the fiscal years ended June 30, 2009 approximated 49% of revenues and were derived from two customers. The balance of revenues in the fiscal year ended June 30, 2009 related to services performed under a contract which concluded on June 30, 2009 with FhCMB for advisory services in connection with the pilot plant. Accounts receivable from the latter represented 89% of the accounts receivable balance as of June 30, 2009. The Company did not have any revenues from these or other customers during the year ended June 30, 2010 and had no receivables outstanding from those customers as of June 30, 2010.

d) Major Vendors and Related Parties

- i) During the year ended June 30, 2009, the Company subcontracted the manufacturing and sales activity of its nutritional supplements to a wholly owned subsidiary of its Former Parent. Substantially all of the Company's cost of goods sold during the year ended June 30, 2009 were paid to this related party. For the fiscal years ended June 30, 2009, the Company was invoiced by the subsidiary of its former parent \$496,400 under this arrangement and such amounts are included in cost of goods sold in the statements of operations.
- ii) During the years ended June 30, 2010 and 2009, the Company utilized the services of FhCMB research and development services as described in Note 5, has commitments to FhCMB as of June 30, 2010 as described in Note 8, and has issued warrants and options to FhCMB and FhCMB's Executive Director, respectively, as described in Note 10. Effective March 1, 2010, that individual and the Company entered into an employment agreement whereby that individual began serving in the additional role of the Company's Chief Scientific Officer.

During the years ended June 30, 2010 and 2009, the Company included in research and development expenses in the statement of operations amounts aggregating approximately \$2,347,000 and \$500,000, respectively, related to costs associated with these relationships. Additionally, as further discussed in Note 8, the Company is indebted to FhCMB in the amount of \$1,350,000 as of June 30, 2010.

- iii) During the year ended June 30, 2010, the Company utilized the services of an entity which one of the Company's officers has a minority investment. During that period, the Company was invoiced \$38,500 by this entity and such amounts are included in research and development expense in the statements of operations.

e) Other Business Risks

The Company insures its business and assets against insurable risks, to the extent that it deems appropriate, based upon an analysis of the relative risks and costs. The Company believes that the risk of loss from non-insurable events would not have a material adverse effect on the Company's operations as a whole.

12) Subsequent Events

In July 2010, the Company issued warrants to a financial advisory firm to purchase 500,000 shares of common stock for a five year period. This warrant vests ratably on a monthly basis beginning with the date of issuance and the following twenty-four month anniversary dates and has an exercise price of \$1.10 per share.

In July 2010, the Company issued warrants to an investor/public relations firm to purchase 300,000 shares of common stock for a five-year period. This warrant was 100% vested upon issuance and has an exercise price of \$1.40 per share.

In July and August 2010, the Company issued options to Directors to purchase 150,000 shares of common stock for a ten year period. These options vest one-third upon the date of issuance and ratably over the following two anniversary dates and have exercise prices ranging from \$1.41 to \$1.73 per share.

In July and August 2010, the Company issued options to employees to purchase 130,000 shares of common stock for a ten year period. These options vest one-third upon the date of issuance and ratably over the following two anniversary dates and have exercise prices ranging from \$1.38 to \$1.73 per share.

In August 2010, the Company issued options to officers to purchase 600,000 shares of common stock for a ten year period. These options vest twenty percent upon the date of issuance and ratably over the following four anniversary dates and have an exercise price of \$1.73 per share.