iBio, Inc. Form 10-K September 28, 2009

## 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, 2009

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission File Number 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:

<u>Title of Each Class</u> Common Stock, \$0.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes | | No | X |

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 | X |

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 | X | 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 | X | 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.

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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 | .. |
Accelerated Filer | .. |
Non-accelerated Filer | .. |
Smaller reporting company | X |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes | | No | X |

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, 2008 was \$1,029,596.

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

Class
Common Stock, \$0.001 par value

Outstanding at September 24, 2009 27,972,904 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

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# 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", "m "would", "could", "should", "seeks", or "scheduled to", or other similar words, or the negative of these terms or other variation 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. Description of Business**

## Overview

iBio, Inc., a Delaware corporation (formerly iBioPharma, Inc.) (the "Company"), is a biotechnology company focused on developing vaccines and therapeutic proteins based upon our proprietary plant-based iBioLaunch<sup>TM</sup> Platform Technology. Our near-term focus is to advance an H1N1 influenza vaccine candidate to clinical trials and to establish business arrangements for use of our technology by licensees for the development and production of products for the prevention and treatment of various infectious diseases including influenza, anthrax and human papilloma virus (HPV).

We believe our technology has broad product applicability, and that through license agreements and technology transfer contracts with companies and government entities to establish regional vaccine manufacturing facilities, we may be able to generate revenue prior to regulatory approval of individual products. We believe this business strategy will reduce product specific risk while advancing the commercial value of our technology and the value of our product candidates. We expect license agreements for commercial rights to our product candidates to produce additional revenue.

Our technology platform was invented and developed by Fraunhofer USA Center for Molecular Biotechnology ("FhCMB"), a not-for-profit translational research institution. In January 2004, we acquired through a Technology Transfer Agreement (as amended) the platform from FhCMB together with FhCMB's commitment for the maintenance and support necessary to further protect the intellectual property comprising the platform, including filing and prosecuting patent applications, providing scientific support for patent counsel's activities on behalf of the Company and otherwise to maintain in force and good standing the Company's intellectual property rights.

In order to attract appropriate licensees and increase the value of the Company's share of such intended contractual arrangements, the Company engaged FhCMB in October 2004 to perform additional research and development activities to apply the platform to create our first product candidate. The Company 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, we believe our technology is applicable to the production of vaccines for any strain of influenza including the newly-emerged strains of H1N1 swine-like influenza. We are currently evaluating how to best approach testing one or more influenza vaccine product candidates.

In addition to the funding we have provided, FhCMB has received additional funding from the Bill & Melinda Gates Foundation for development of an experimental vaccine for H5N1 avian influenza based upon our iBioLaunch<sup>TM</sup> Platform Technology. A Phase 1 clinical trial of this avian candidate vaccine is expected to begin mid-calendar year 2010, and we expect to test a candidate vaccine for H1N1 swine-like influenza in late calendar year 2010.

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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 for this engagement was to demonstrate the ease and economy with which platform-based products could be manufactured, again in order to attract potential licensees and increase the value of the Company's share of 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 is nearing completion in the FhCMB facility in Newark, Delaware. This facility and equipment in this facility is currently undergoing validation for cGMP production. Once validation of the facility is complete, it will be used for pilot scale cGMP production of protein targets for clinical trials of product candidates utilizing our platform technology.

We have 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 (collectively, 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 of which they granted or were granted funding, and (b) to FhCMB for research purposes and applications in other fields.

This business structure helps us to enhance the commercial rights and the scope of applications of our platform technology. It also helps us demonstrate the validity and apparent value of the platform to parties to whom we will offer licenses or other business opportunities. Outsourcing our research and development work allows us 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 our own research and development staff and facilities.

Currently, all of our product candidates were in the preclinical development stage. We sometimes refer to the platform technology as "iBioLaunch<sup>TM</sup> technology" or the "iBioLaunch<sup>TM</sup> platform," and we refer to the category of this technology a "plant-based technology" or as a "plant-based platform."

We have 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 expansion of production capabilities, 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) creates potential for our platform technology to be used by potential licensees to enter the market utilizing what we expect to be an economical production system. We currently have no commercial partners for this category of products and we are 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, we have 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. We utilized the services of various wholly-owned subsidiaries of our former parent company, Integrated BioPharma, Inc., ("Integrated BioPharma" or "Former Parent") to support us in the production, marketing and sales of these phytomineral products.

Effective April 1, 2009, we entered into an agreement with IHT Health Products, Inc. (a wholly owned subsidiary of our Former Parent) ("IHT") wherein we 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 have been 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 our 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 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. This is currently our only business relationship. The termination of this arrangement might adversely affect our ability to develop and commercialize our product candidates.

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 \$16.4 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).

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, Approximately \$8.7 of the funding provided to FhCMB by the Bill & Melinda Gates Foundation is to fund clinical trials of the pandemic flu candidate based upon the Company's 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 the Company's technology. We may decide to commercially license such technology to advance into human clinical evaluation and eventual commercial development. The U.S. Department of Defense ("DoD") has also provided \$10.3 million in funding to FhCMB for preclinical and clinical studies for anthrax and plague vaccine projects, and this funding is similarly beneficial to us because we have retained the commercial rights to any technology improvements resulting from those projects.

Pursuant to the Technology Transfer Agreement between the Company and FhCMB, effective as of January 1, 2004, we paid \$3,600,000 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. To date, two United States patent have been granted, and 17 are pending in 14 patent families. Foreign patent applications corresponding to many of these applications are pending in various countries.

The Company's 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 products applicable to a broad range of disease

agents, such as influenza, sleeping sickness, anthrax, plague, HPV, and veterinary influenza applications.

By certain subsequent agreements, the Company engaged FhCMB to perform certain research activities for which the Company makes payments when certain milestone tasks have been performed; such payments are conditioned only on the performance of the task, not upon the success or value of what is determined or discovered.

At various times since January 2004, we amended our agreements with FhCMB. These amendments include a commitment by FhCMB to further develop exclusively for and transfer to the Company 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 the Company has 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 the Company for the same purposes.

In addition, the Company is required to make royalty payments to FhCMB equal to 1% of all receipts derived by the Company from sales of products utilizing the proprietary technology and 15% of all receipts derived by the Company 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 the Company royalty payments equal to 9% of all receipts, if any, realized by FhCMB from sales, licensing or commercialization of the intellectual property licensed from iBio.

We participated with FhCMB from May 2007 through June 2009 on a contract from DARPA (Defense Advanced Research 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 through its application 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. We estimate that at least one product candidate based on our technology will enter Phase I human clinical testing during calendar 2010.

<u>Seasonal and H1N1 Influenza Vaccines</u>. 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 the recently emerged H1N1 swine-like influenza 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. Our near-term objective is to complete preclinical evaluation and transition selected vaccine candidates into Phase 1 human clinical trials.

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<sup>TM</sup> 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 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 in the scientific journal *Vaccine*, 2007 Apr 20; 25(16):3018-21. We do not intend additional investment in this product candidate until either we identify a commercial sponsor of this

program, or until we determine that our capital resources are sufficient to resume development without slowing our influenza product development priorities.

<u>Biodefense Products</u>. 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.

Under Department of Defense sponsorship, FhCMB conducted rabbit and non-human primate studies on a proprietary multi-agent anthrax and plague vaccine. FhCMB also developed a proprietary antibody for potential treatment of anthrax infections. A study in non-human primates demonstrated 100% protection against challenge with anthrax spores, and dose de-escalation studies are currently underway. We have exclusive commercial rights to these product candidates for use in human health. We have not established any commercial relationships for further development of these products and do not intend additional investment in this product until we identify a commercial sponsor of this program.

<u>Vaccines for Developing Markets</u>. 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 certain therapeutic proteins. We provide summary information on product markets of interest to us in subsequent paragraphs. However, our current business focus is primarily on establishing the necessary capability, information and 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 assume 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, but we have not attempted to quantify such hypothetical demand for access to our platform technology for general biotechnology product manufacturing purposes.

Vaccines are well established in clinical practice, and the route to regulatory approval for product marketing is clear based on guidance documents issued by the FDA and available at the FDA's website, www.fda.gov. We have focused our expertise on two important markets, influenza and HPV. We also believe our platform is useful for the development of products for

diseases of potential bioterrorism importance (most of which also are serious health problems in the developing world).

<u>Influenza Market</u>. We believe that we can achieve commercial success by applying our platform technology to 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 \$4.9 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.

<u>Biodefense Market</u>. 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.

#### **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. We believe that our technology is applicable to 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 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 the Company 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.

# **Intellectual Property**

iBioPharma exclusively controls 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.

For the intellectual property developed by FhCMB, we currently hold two issued U.S. patents, one for inducing gene silencing in plants and one for transient expression of genes for foreign proteins, such as vaccine antigens, in plants which expire in 2022 and 2025, respectively. We have an additional 17 U.S. patent applications pending. Similarly, we are preparing patent

applications relating to our expanding technology for filing in the U.S. and abroad. We have also applied for patents in numerous foreign countries, including Europe, Canada, Australia, China, India, Brazil, Japan, Hong Kong and New Zealand. We currently have 93 pending foreign patent applications. The following summarizes the issued and pending patent applications on our technology and products:

# 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

While we have not established commercial licenses for our platform technology and while we currently have not yet entered into Phase 1 studies with any of our product candidates, we expect to commercialize our first influenza product through a business agreement with one or more larger firms. We have established no such agreements, and we currently expect to obtain Phase 1 or equivalent human clinical data before negotiating license or marketing agreements for product candidates. 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.

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.

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.

We have no experience in the sales, marketing and distribution of pharmaceutical products or in commercial technology transfer operations. If in the future we fail to establish commercial licenses for our platform technology or we fail to reach or elect not to enter into an arrangement with a partner 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 market such products directly. Significant additional expenditures would be required for us to develop such an in-house sales and marketing organization.

# 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 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 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 antibody candidates that are undergoing clinical trials and for the diseases and conditions that are subjects of our preclinical development program. For example, the drugs oseltamivir, amantadine, and zanamivir are used to treat certain influenza infections, and Merck's vaccine to prevent HPV infection has been approved by the FDA with a similar vaccine developed by GlaxoSmithKline in late-stage development. 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 all of our product candidates are likely to be their 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 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, see their 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 1 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 the Spin-off, 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 the Company's 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 September 24, 2009, we had two full-time employees and one part-time employee. 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 our employees. We expect our

number of employees to remain unchanged during the next twelve months. 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 <a href="www.ibioinc.com">www.ibioinc.com</a> . 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

#### **Risks Related to Our Business**

Our plant-based technology platform has not previously been used by others to successfully develop 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, the Company will not generate the revenues presently contemplated by its business plan to support its continuing operations.

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 continue our business operations.

We have five internal product candidates and two additional categories--biodefense and developing world--made through the application of our technology platform, none of which has entered human clinical trials and for none of which an investigational new drug application (IND) has been filed with the FDA. Our success in establishing licenses to our platform will substantially depend on our ability to successfully complete clinical trials, obtain 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.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans.

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

- · Our preclinical or clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical testing or clinical trials or to abandon projects that we expect to be promising. For example, we may obtain promising animal data about the immunogenicity of a vaccine candidate and then our human tests may result in no or inadequate immune responses. In addition, we may encounter unexpected safety concerns 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, we may obtain data that suggest a desirable immune response from one of our vaccine candidates in a small human study, but then when tests are conducted on larger numbers of people, we may not see the same extent of immune response. 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 clinical trials may be slower than we currently anticipate, resulting in significant delays. The cost of conducting a clinical trial increases as the time required to enroll adequate numbers of human subjects to obtain meaningful results increases. Enrollment in a clinical trial can be a slower-than-anticipated process because of competition from other clinical trials, because the study is not of interest to qualified subjects, or because the stringency of requirements for enrollment limits the number of people who are eligible to participate in the clinical trial.
- · We might have to suspend or terminate our 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. We will not know the risk of any candidate product 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 we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable.
- · The effects of our product candidates may not be the desired effects or may include undesirable side effects.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our product candidates, we may not be able to obtain marketing approval or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether planned clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates. 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 shepherd our product candidates through the clinical testing process and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly as the scope of the clinical trials that we are conducting expands. In addition, subject to regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. 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 research and 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 fall of 2010. Our future funding requirements will depend on many factors, including:

- the scope and results of our clinical trials;
- our ability to advance additional product candidates into development;
- the success of our anticipated commercial agreements with pharmaceutical Companies;
- 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 product 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 of our product candidates are successfully completed, we will be able to submit a biologics license application (BLA), to the FDA or that any BLA we submit 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 fail to commercialize any of our product candidates, 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.

If commercialized, our product candidates may not be approved for sufficient governmental or third-party reimbursements, which would adversely affect our ability to market our product candidates.

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Since we currently have no commercial products, we have not had to face this issue yet; however, third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers for any of our product candidates. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may negatively affect the marketing of our potential products.

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. 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 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 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.

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 that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. For example, the drugs oseltamivir, amantadine, and zanamivir are used to treat certain influenza infections, and Merck's vaccine to prevent HPV infection has been approved by the FDA with a similar vaccine developed by GlaxoSmithKline in late-stage development. 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 all of our product candidates are likely to be their efficacy, safety profile, price and convenience.

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 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:

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

The Company 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 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 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 or our licensors' 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. To date, we have 17 U.S. applications pending and 93 applications pending in Europe, Canada, Australia, China, India, Brazil, Japan, Hong Kong and New Zealand for the intellectual property developed by FhCMB. 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 "Description of 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 "Description of 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 products 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;
- 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 distribution, we and Integrated BioPharma entered into a number of agreements that govern our spin-off from Integrated BioPharma 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, including, but not limited to:

- · an 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 entering into with Integrated BioPharma in connection with the distribution and for any of our liabilities; and
- · an agreement with regard to tax matters between ourselves and Integrated BioPharma which restricts our ability to engage in certain strategic or capital raising transactions.

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

It is possible that our quarterly revenues and operating results may vary significantly in the future and that period-to-period comparisons of our revenues and 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 revenues and 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.

Current economic conditions may cause a decline in business and consumer 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, etc. Additionally, we may experience difficulties in scaling our operations to react to economic pressures in the U.S.

# **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. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended June 30, 2009.

#### **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.OB".

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

	High	Low
First quarter	\$2.00	\$1.00
Second quarter	\$1.00	\$0.11
Third quarter	\$0.31	\$0.12
Fourth quarter	\$0.69	\$0.20

# **Holders**

As of June 30, 2008, the Company was a wholly owned subsidiary of Integrated BioPharma, Inc. On August 18, 2008, the distribution date from Integrated BioPharma, and June 30, 2009 there were approximately 1,000 holders of record of the Company's 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, 2008 and 2009 nor does the Company anticipate paying dividends in the foreseeable future.

## **Equity Compensation Plans**

The Company does not currently have any shares issued under equity compensation plans.

#### **Recent Sales of Unregistered Securities**

On July 13, 2009, the Company issued a five-year warrant to purchase up to 100,000 shares of its common stock to a financial advisor. The warrant and the common stock issuable upon exercise of the warrant have not been registered under the Securities Act and were issued and sold in reliance upon the exemption from registration contained in Section 4(2) of the Securities Act and Regulation D promulgated thereunder. These securities may not be offered or sold in the United States in the absence of an effective registration statement or exemption from the registration

requirements under the Securities Act.

#### Item 6. Selected Financial Data

Not Applicable

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

You should read the following discussion in conjunction with the audited financial statements and corresponding notes, and the unaudited pro forma financial statements and corresponding notes, found elsewhere in this information statement. This section of the Annual Report, Form 10-K contains forward-looking statements. Please see the section titled "Cautionary Note Regarding Forward-looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements.

#### Overview

iBio, Inc., a Delaware corporation, (formerly iBioPharma, Inc.) (the "Company") is a biotechnology company focused on developing vaccines and therapeutic proteins based upon our proprietary plant-based iBioLaunch<sup>TM</sup> Platform Technology. Our near-term focus is to advance an H1N1 influenza vaccine candidate to clinical trials and to establish business arrangements for use of our technology by licensees for the development and production of products for the prevention and treatment of various infectious diseases including influenza, anthrax and human papilloma virus (HPV).

We believe our technology has broad product applicability, and that through license agreements and technology transfer contracts with companies and government entities to establish regional vaccine manufacturing facilities, we may be able to generate revenue prior to regulatory approval of individual products. We believe this business strategy will reduce product specific risk while advancing the commercial value of our technology and the value of our product candidates. We expect license agreements for commercial rights to our product candidates to produce additional revenue.

Our technology platform was invented and developed by Fraunhofer USA Center for Molecular Biotechnology ("FhCMB"), a not-for-profit translational research institution. In January 2004, we acquired through a Technology Transfer Agreement (as amended) the platform from FhCMB together with FhCMB's commitment for the maintenance and support necessary to further protect the intellectual property comprising the platform, including filing and prosecuting patent applications, providing scientific support for patent counsel's activities on behalf of the Company and otherwise to maintain in force and good standing the Company's intellectual property rights.

In order to attract appropriate licensees and increase the value of the Company's share of such intended contractual arrangements, the Company engaged FhCMB in October 2004 to perform research and development activities to apply the platform to create our first product candidate. The Company 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, we believe our

technology is applicable to the production of vaccines for any strain of influenza including the newly-emerged strains of H1N1 swine-like influenza. We are currently evaluating how to best approach testing one or more influenza vaccine product candidates.

In addition to the funding we have provided, FhCMB has received additional funding from the Bill & Melinda Gates Foundation for development of an experimental vaccine for H5N1 avian influenza based upon our iBioLaunch<sup>TM</sup> Platform Technology. A Phase 1 clinical trial of this candidate vaccine is expected to begin in the calendar year 2010, and we expect to test a candidate vaccine for H1N1 swine-like influenza during calendar year 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 for this engagement was to demonstrate the ease and economy with which platform-based products could be manufactured, again in order to attract potential licensees and increase the value of the Company's share of 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 is nearing completion in the FhCMB facility in Newark, Delaware. This facility and equipment in this facility is currently undergoing validation for cGMP production. Once validation of the facility is complete, it will be used for pilot scale cGMP production of protein targets for clinical trials of product candidates utilizing our platform technology.

We have 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 (collectively, 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 of which they granted or were granted funding, and (b) to FhCMB for research purposes and applications in other fields.

This business structure helps us to enhance the commercial rights and the scope of applications of our platform technology. It also helps us demonstrate the validity and apparent value of the platform to parties to whom we will offer licenses or other business opportunities. Outsourcing our research and development work allows us 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 our own research and development staff and facilities.

As of August 31, 2009, all of our product candidates were in the preclinical development stage. We sometimes refer to the platform technology as "iBioLaunch<sup>TM</sup> technology" or the "iBioLaunch<sup>TM</sup> platform," and we refer to the category of the technology as "plant-based technology" or as a "plant-based platform."

We have 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 expansion of production capabilities, 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) creates potential for our platform technology to be used by potential licensees to enter the market utilizing what we expect to be an economical production system. We currently have no commercial partners for this category of products and we are 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, we have 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. Immediately after the spin-off, we engaged the services of various wholly-owned subsidiaries of Integrated BioPharma, Inc., ("Integrated BioPharma" or "Former Parent") formerly our parent company, to support us in the production, marketing and sales of these phytomineral products.

Effective April 1, 2009, we entered into an agreement with IHT Health Products, Inc. (a wholly owned subsidiary of our Former Parent) ("IHT") wherein we 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 have been beneficially transferred to IHT. Until formal transfer of the agreements, the Company will act as IHT's agent thereunder.

# Effect of Spin-off from Integrated BioPharma, Inc.

After the distribution, which occurred on August 18, 2008, the contribution of additional capital from Integrated BioPharma., our Former Parent, and the \$5.0 million private placement, Integrated BioPharma owns approximately 5.4% of our common stock, and ceased to control iBioPharma.

As described in the preceding section, we historically sold nutritional supplements which were manufactured by a subsidiary of Integrated BioPharma, our former parent. Effective April 1,

2009, we licensed the related technology and rights to a subsidiary of our Former Parent in exchange for a 5% royalty on sales of such products.

#### **Critical Accounting Policies and Estimates**

#### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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. The most significant estimates include:

- · Stock-based compensation;
- Valuation and recoverability of intangible assets, including the values assigned to acquired intangible assets;
- · Income taxes and valuation allowance on deferred income taxes, and;
- · Accruals for contingent liabilities, if any.

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.

**Revenue Recognition.** The Company recognizes revenue when the following four criteria under the Staff Accountant's Bulletin ("SAB 104") have been met: (i) persuasive evidence that an arrangement exists, (ii) the product has been shipped or the service has been performed and the Company has no significant remaining obligation, (iii) the seller's price to the buyer is fixed or determinable and (iv) collectability is reasonably assured.

**Stock-Based Compensation.** The Company accounts for stock-based compensation in accordance with SFAS No. 123(R), share based payment. Under the fair value recognition provision, of this statement, share-based compensations cost is measured at the grant date based on the fair value of the award and is recognized as expense over the applicable vesting period of the stock award using the straight line method

Income Taxes. The Company accounts for income taxes using the liability method in accordance with the provisions of FASB Statement No. 109, "Accounting for Income taxes". 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 Per Share*. In accordance with FASB Statement No. 128, "Earnings Per Share," basic earnings per common share are based on weighted average number of common shares outstanding. Diluted earnings per share amounts are based on the weighted average number of common shares outstanding, plus the incremental shares that would have been outstanding upon the assumed exercise of all potentially dilutive stock options, warrants and convertible preferred stock, subject to anti-dilution limitations. For the fiscal years ended June 30, 2009 and 2008, the Company did not have any derivative securities outstanding which would result in the dilution of earnings per share.

Fair Value of Financial Instruments. Generally accepted accounting principles require disclosing the fair value of financial instruments to the extent practicable for financial instruments which are recognized or unrecognized in the balance sheet. The fair value of the financial instruments disclosed herein is not necessarily representative of the amount that could be realized or settled, nor does the fair value amount consider the tax consequences of realization or settlement. In assessing the fair value of financial instruments, the Company uses a variety of methods and assumptions, which are based on estimates of market conditions and risks existing at the time. For certain instruments, including cash, accounts receivable, notes receivable, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

Intangible Assets. Intangible assets consist of intellectual property and trademarks and patents. Amortization is being recorded on the straight-line basis over periods ranging from 10 years to 20 years based on contractual or estimated lives. The useful life of an intangible asset is the period over which the asset is expected to contribute directly or indirectly to future cash flows. In accordance with the provisions of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the carrying value of intangible assets is evaluated whenever events or circumstances indicate that the carrying value may not be recoverable or at least on an annual basis. The carrying value is not recoverable when the projected undiscounted future cash flows are less than the carrying value. Tests for impairment or recoverability require significant management judgment, and future events affecting cash flows and market conditions could result in impairment losses. In the fiscal years ended June 30, 2009 and 2008, no impairment losses were indicated or recorded.

Contingent Liabilities. The Company records liabilities in accordance with the provisions of Statement of Financial Accounting Standards No. 5, "Accounting for Contingencies" when it is probable a liability has been incurred and the amount can re reasonably estimated or determined. In the fiscal years ended June 30, 2009 and 2008, no accruals or expenses for contingent liabilities were recorded.

# **Recent Accounting Pronouncements**

In April 2008, the FASB issued FASB Staff Position (FSP) SFAS No. 142-3, "Determination of the Useful Life of Intangible Assets". FSP FAS No. 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets" and was effective for fiscal years beginning after December 15, 2008. The adoption of this pronouncement by the Company for the fiscal year ending June 30, 2010 will not have a material impact on the its financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ("SFAS 165"). SFAS 165 establishes general standards for accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or available to be issued and was effective for interim and annual periods ending after June 15, 2009. The adoption of SFAS No. 165 did not have an impact on the Company's results of operations or financial condition. The Company evaluated all subsequent events that occurred from July 1, 2009 through September 28, 2009, inclusive, and disclosed all material subsequent events in Note 11.

In June 2009, the FASB issued SFAS No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" ("SFAS No. 168"). SFAS No. 168 will become the single source of authoritative nongovernmental U.S. generally accepted accounting principles ("GAAP"), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force ("EITF"), and related accounting literature. SFAS No. 168 reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections. SFAS No. 168 will be effective for financial statements issued for reporting periods that end after September 15, 2009. The adoption of SFAS No. 168 is not expected to have a material impact on the Company's consolidated results of operations and financial condition.

# **Results of Operations**

#### Fiscal year ended June 30, 2009 compared to the fiscal year ended June 30, 2008

**Net Sales.** Net sales for the fiscal year ended June 30, 2009 and 2008 were \$1,177,000 and \$987,000, respectively, an increase of \$190,000 or 19%. Sales under our supply agreement with Mannatech represented 49% and 92% for the fiscal years ended June 30, 2009 and 2008, respectively. This decrease is attributable to the inclusion of sales from FhCMB during the year ended June 30, 2009 as described in the following paragraph.

For the fiscal year ended June 30, 2009, nutraceutical sales under our supply agreement with Mannatech were derived from two customers, L. Perrigo Company (14%) (formerly, JB Laboratories, Inc.) and Natural Alternatives International (35%). They became our customers under our supply agreement with Mannatech at the direction of Mannatech for the purpose of supplying certain raw materials in the manufacturing process of Mannatech's nutraceutical product lines. The remaining customer during the year ended June 30, 2009, FhCMB, represented 49% of net sales and relates to our subcontract agreement with FhCMB under their

DARPA (Defense Advanced Research Agency) grant. Our subcontract agreement with FhCMB concluded on June 30, 2009. For the fiscal year ended June 30, 2008, the majority of sales under our supply agreement with Mannatech were derived from the same two customers, L. Perrigo Company (41%) and Natural Alternatives International (51%).

Effective April 1, 2009, the Company licensed the technology related to the nutraceutical sales and transferred the customer relationships to a subsidiary of its Former Parent in consideration for a 5% royalty on net sales.

**Cost of sales.** Cost of sales increased to \$501,000 for the fiscal year ended June 30, 2009, as compared to \$485,000 for the fiscal year ended June 30, 2008. Cost of sales, as a percentage of sales, were 42% and 49%, respectively, for the fiscal years ended June 30, 2009 and 2008.

**Research and Development Costs.** Our research and development costs were \$797,000 in the fiscal year ended June 30, 2009 compared to \$550,000 in the fiscal year ended June 30, 2008. Research and development costs consist primarily of payments made or owed to FhCMB in reaching milestones under our research agreements with them. The increase of \$247,000 was primarily the result in a \$250,000 increase of payments made to FhCMB under our research agreements with them.

**Selling and Administrative Expenses.** Selling and administrative expenses were \$1,805,000 for the fiscal year ended June 30, 2009, a decrease of \$13,000 or 1% as compared with \$1,818,000 for the fiscal year ended June 30, 2008. A tabular presentation of the changes in selling and administrative expenses is as follows:

Corporate support charges from Integrated BioPharma decreased to approximately \$23,000 in the fiscal year ended June 30, 2009 from approximately \$315,000 from the fiscal year ended June 30, 2008, a decrease of approximately \$291,000 or 93% due to the fact that such charges ceased as of the August 18, 2008, the distribution date of the spin-off from our Former Parent.

Corporate support charges consisted of the following:

In December 2006, the Company made in an investment in a private biotech company that was in its initial stages of filing to become a public company. In the fiscal year ended June 30, 2008, the Company, based in part on information from public filings of the biotech company, charged off its entire investment, \$254,000, in this biotech company.

Salaries and employee benefits increased to \$614,000 in the fiscal year ended June 30, 2009 from \$351,000 in the fiscal year ended June 30, 2008, an increase of approximately \$263,000 or 75%. The increase is attributable to the Company's continued expansion of its operations and staff. The number of employees increased from five during the fiscal year ended June 30, 2008, some of which were only employed during a portion of that year, to seven during the fiscal year ended June 30, 2009, all of which were employed throughout that entire year. Subsequent to June 30, 2009, the number of employees decreased to three as several employees joined FhCMB as agreed to by all parties.

Depreciation and amortization expense increased to approximately \$284,000 in the fiscal year ended June 30, 2009 from approximately \$245,000 in the fiscal year ended June 30, 2008, or approximately \$39,000 or 16%. The increase is due to continued capitalization of patent costs during the year ended June 30, 2009 and an increase in the related amortization expense.

Lab expense decreased to \$57,000 in the fiscal year ended June 30, 2009 from \$117,000 in the fiscal year ended June 30, 2008, a decrease of approximately \$60,000 or 51%. This decrease is primarily attributable to a reduction in lab supplies of \$37,000.

Travel and entertainment expenses decreased to \$90,000 in the fiscal year ended June 30, 2009 from \$96,000 in the fiscal year ended June 30, 2008, a decrease of approximately \$6,000 or 6%. A substantial portion of such costs is attributable to the geographical diversity of our management team and the costs related to their travel requirements. For example, our corporate office is located in Delaware, our president resides in California, and our Chief Scientific Officer resides in London. Such expenses are comparable to the prior year.

Consulting and other professional fees increased to \$609,000 in the fiscal year ended June 30, 2009 from \$291,000 in the fiscal year ended June 30, 2008, an increase of \$318,000 or 109%. This increase is primarily attributable to increases in legal fees of \$136,000, audit fees of \$110,000, and ongoing accounting and reporting support provided by our Former Parent of \$90,000 all related to and incurred after the August 18, 2008 spin-off from our Former Parent. Prior to that date, all expenses of this nature were included in the overhead portion of corporate support charges.

Stock-based compensation expense decreased to \$13,000 in the fiscal year ended June 30, 2009 from \$56,000 in the fiscal year ended June 30, 2008, a decrease of \$43,000 or 77%. Stock-based compensation expense in the fiscal years ended June 30, 2009 included \$8,000 related options issued by the Company in the period after the date of the spin-off from the Former Parent. Stock-based compensation expense in the fiscal years ended June 30, 2009 and 2008 included \$5,000 and \$56,000, respectively, allocated from our Former Parent for our employees and directors who received compensation in the form of stock options providing for the purchase of our Former Parent's stock upon vesting of their awards.

Other expense increased to approximately \$115,000 in the fiscal year ended June 30, 2009 from approximately \$93,000 in the fiscal year ended June 30, 2008, approximately \$22,000 or 24%. As a percentage of total selling and administrative expenses, other expenses were 6% and 5% in the fiscal years ended June 30, 2009 and 2008, respectively.

**Income tax (benefit).** The Company had net income tax expense of approximately \$2,000 in the fiscal year ended June 30, 2009 compared to \$4,000 in the fiscal year ended June 30, 2008. Our ability to recognize an income tax benefit related to operations through August 18, 2008, the date of the spin-off from Integrated BioPharma, is dependent on the consolidated federal taxable income (loss) of our Former Parent's controlled group for federal income tax purposes. Similarly, our ability to recognize an income tax benefit related to operations after August 18, 2008 is dependent on our federal tax position.

In the fiscal year ended June 30, 2009 and 2008, the controlled group of Integrated BioPharma had a taxable loss and therefore did not utilize any of the losses generated by us through August 18, 2008 or after that date as a stand-alone taxable entity. Therefore, we reserved 100% of our resulting deferred tax asset generated from the net operating loss during the fiscal year ended June 30, 2009 as it is more likely than not that, in the near term, that neither we nor our Former Parent will generate sufficient taxable income to offset our Fiscal 2009 and 2008 taxable losses. As of June 30, 2009, our deferred tax assets relating to our federal and state net operating losses are fully reserved in a valuation allowance account since it is more likely than not that neither we or our Former Parent will not have sufficient taxable income in the near future to offset any future taxable income.

#### **Seasonality**

We do not believe that our operations are impacted by seasonality.

# Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations during fiscal 2009. The Company had an accumulated deficit of approximately \$8,668,000 as of June 30, 2009 and cash outflows from operating activities of approximately \$2,025,000 for the year then ended. The Company has historically financed its activities from operations through the private placement of its equity securities. To date, the Company has dedicated most of its financial resources to research and development as well as general and administrative expenses.

Cash and cash equivalents as of June 30, 2009 were approximately \$1,039,000. Subsequent to that date, the Company closed on a private placement of its equity securities in September 2009 providing net proceeds of \$2,833,000. Management believes that the existing cash balance together with its other existing financial resources will be sufficient to meet the Company's operating and capital requirements beyond the end of the first quarter of fiscal 2011. The fiscal 2010 operating plan reflects the Company's \$2,000,000 contractual commitment to FhCMB under the Technology Transfer Agreement as described in Note 8. The Company has developed and could implement contingency plans to reduce its operation expense should circumstances require, though there can be no assurance that such plans will maintain adequate liquidity and prevent the possible impairment of assets.

The Company's historical operating results cannot be relied on to be an indicator of future performance, and management cannot predict whether the Company will achieve or sustain positive operating cash flows or generate net income in the future.

The following table sets forth, for the periods indicated, the Company's net cash flows used in operating, investing and financing activities:

At June 30, 2009, we had working capital of \$723,000, an increase from our negative working capital of \$1,761,000, as of June 30, 2008. The increase in our cash position to \$1,039,000 as of June 30, 2009 is attributable to the fundraising in August 2008 less operating and investing expenses since that date. In prior years, our cash position was minimal as our Former Parent advanced funds to our operating account on an as needed basis.

In the fiscal year ended June 30, 2009, we used \$2,025,000 of cash in our operating activities compared to \$1,149,000 in the prior year, an increase of approximately \$876,000. This change is primarily attributable to an increase in our operating loss of \$296,000 (excluding non-cash activities), an increase in the use of cash of \$145,000 related to accounts receivable, and an increase in the use of cash of \$494,000 related to accounts payable and accrued expenses.

The increase in our accounts receivable balance is primarily attributable to invoices due from FhCMB whose payment has been delayed due to administrative matters related to the contract extension through June 30, 2009. The increases in the use of cash related to account payable and accrued expenses is primarily attributable to the payment of outstanding liabilities during the fiscal year ended June 30, 2009.

In the fiscal year ended June 30, 2009, we used \$1,617,000 of cash in our investing activities compared to \$288,000 in the prior year, an increase of \$1,329,000. This change is primarily attributable to an increase in the use of cash of \$275,000 related to additions to intangible assets and an increase in the use of cash of \$1,050,000 related to payments due under the terms of an agreement to purchase intellectual property.

In the fiscal year ended June 30, 2009, we received \$4,662,000 of cash from our financing activities compared to \$1,437,000 in the prior year, an increase of \$3,225,000. This change is primarily attributable to an increase in the receipt of cash of \$4,580,000 related to the sale of common stock and warrants in August 2008 offset by the use of cash of \$1,355,000 related to the repayment of advances due to our Former Parent.

The Company's future commitments as of June 30, 2009 consist of expected payments to FhCMB under our amended technology transfer and research agreements and are expected to be paid in the following time periods:

Less than one year	\$ 2,000,000
One to three years	4,000,000
Four to five years	4,000,000
Six years or more	-
Total	\$ 10,000,000

Our plans to expand our business and to continue to improve our product candidates to strengthen our ability to obtain licensees for our proprietary technology may require funds in excess of our cash flow and may require us to seek financing from third parties. In the past, Integrated BioPharma has provided capital for our general corporate purposes, and we used cash provided by Integrated BioPharma to fund our operations. After the distribution, Integrated BioPharma will not provide funds to finance our operations. Without the opportunity to obtain financing from Integrated BioPharma, we will in the future need to obtain additional financing from banks, or through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements. The terms, interest rates, costs and fees of new credit facilities may not be as favorable as those historically enjoyed with Integrated BioPharma. For example, Integrated BioPharma did not charge us with any fees or costs for the intercompany borrowing, nor were there any covenants regarding financial ratios or prohibition on certain transactions in the loan arrangement with Integrated BioPharma. Our inability to obtain financing on favorable terms could restrict our operations and increase our losses.

In September 2009, we closed on a \$3.0 million private placement (net proceeds of \$2.8 million). This additional capital is expected to cover our anticipated costs through the fall of calendar year 2010. If we are unsuccessful in raising additional capital, securing other alternative financing, or generating licensing revenue, we might have to defer or abandon our efforts to commercialize the intellectual property and cease operations.

#### Capital Expenditures

The Company's capital expenditures, other than intellectual property, during the fiscal years ended June 30, 2009 and 2008 were not material.

#### Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

#### **Recently Announced Accounting Pronouncements**

Please refer to Note 2 in our financial statements which can be found at page 52, herein.

# **Impact of Inflation**

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

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

In the normal course of business, the Company is party to financial instruments that are subject to market risks arising from changes in interest rates. The Company's use of derivative instruments is very limited and it does not enter into derivative instruments for trading purposes.

# **Item 8. Financial Statements**

For a list of financial statements filed as part of this report, see the index tofinancial statements at page 45.

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

None.

#### Item 9A. Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act of 1934 (the "Exchange Act") is recorded, processed, summarized, and reported within the time periods specified by the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, the Company has evaluated the effectiveness of its

disclosure controls and procedures (as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2009, and, based upon this evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these controls and procedures are effective in providing reasonable assurance of compliance.

Changes in Internal Control over Financial Reporting

Under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, the Company has evaluated changes in internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2009 and have concluded that no change has materially affected, or is reasonably likely to materially affect, 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 an adequate system of internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes, in accordance with generally accepted accounting principles. Because of 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 policies and procedures may deteriorate.

The Company's management, including the Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of its internal control over financial reporting as of June 30, 2009 based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, management concluded that our internal control over financial reporting was effective as of June 30, 2009.

The information set forth in this Item 9A shall not be considered filed under the Exchange Act. This annual report does not include an attestation report of Amper, Politziner & Mattia, LLP, the Company's independent registered public accounting firm, regarding internal control over financial reporting. Management's report was not subject to attestation by Amper, Politziner & Mattia, LLP pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this Form 10-K.

#### Item 9B. Other Information

None.

#### **PART III**

# Item 10. Directors and Executive Officers of the Registrant.

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, 2009.

#### **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, 2009.

# 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, 2009.

# Item 13. Certain Relationships and Related Transactions

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, 2009.

## **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, 2009.

#### **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.
- 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)
- 21 Subsidiaries of the Registrant (7)
- 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. 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.

# **Item 8: Financial Statements**

# IBIO, INC. (Formerly iBioPharma, Inc.)

# INDEX TO FINANCIAL STATEMENTS

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#### **Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders of

iBio, Inc.

We have audited the accompanying balance sheets of iBio, Inc, (formerly iBioPharma, Inc.) as of June 30, 2009 and 2008 and the related statements of operations, stockholders' equity (deficiency), and cash flows for each of the years 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 audits.

We conducted our audits 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 audits provide 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 2008, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Amper, Politziner & Mattia, LLP September 28, 2009 Edison, New Jersey Edgar Filing: iBio, Inc. - Form 10-K IBIO, INC.

(Formerly iBioPharma, Inc.)

# NOTES TO FINANCIAL STATEMENTS AS OF JUNE 30, 2009 AND 2008 AND FOR THE FISCAL YEARS ENDED

**JUNE 30, 2009 AND 2008** 

# Note 1. Business, Basis of Presentation and Liquidity

iBio, Inc. (the "Company") is a biotechnology company focused on developing its proprietary plant-based technology for application to vaccines and therapeutic proteins. The Company's near-term focus is on establishing business arrangements for use of our technology by licensees for the development and production of products for the prevention and treatment of various infectious diseases including influenza, anthrax and human papilloma virus (HPV). 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 April 1, 2009, 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 5% royalty on future net sales.

iBio, Inc., a Delaware Corporation, changed its name from iBioPharma, Inc. effective August 10, 2009. This name change was effected through a short form merger pursuant to General Corporation law of the State of Delaware by merging into a wholly-owned subsidiary formed solely for the purpose of implementing the name change. This merger had no effect upon our outstanding shares of common stock. The term "Company" refers to iBio, Inc. and its predecessors as described below.

iBioPharma, Inc. was formerly known as InB:Biotechnologies, Inc., a New Jersey corporation and was a wholly owned subsidiary of Integrated BioPharma, Inc. (the "Former Parent" or "Integrated BioPharma") prior to the spin-off from the Former Parent as described below.

On 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 July 2008 our Former Parent announced the spin-off of the Company in the form of a dividend to its stockholders. The record date of the dividend was August 12, 2008 with a distribution date of August 18, 2008. Stockholders of our Former Parent received one share of the Company's common stock for each share of common stock they owned of our Former Parent as of the record date. See Note 9 for additional information.

Immediately following the spin-off, the Company became a public company with stock traded on the OTC Bulletin Board under the symbol IBPM.

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

The Company has incurred significant losses and negative cash flows from operations during fiscal 2009. The Company had an accumulated deficit of approximately \$8,685,000 as of June 30, 2009 and cash outflows from operating activities of approximately \$2,025,000 for the year then ended. The Company has historically financed its activities from operations through the private placement of its equity securities. To date, the Company has dedicated most of its financial resources to research and development as well as general and administrative expenses.

Cash as of June 30, 2009 was approximately \$1,039,000. Subsequent to that date, the Company closed on a private placement of its equity securities in September 2009 providing net proceeds of \$2,833,000. Management believes that the existing cash balance together with its other existing financial resources will be sufficient to meet the Company's operating and capital requirements beyond the end of the first quarter of fiscal 2011. The fiscal 2010 operating plan reflects the Company's \$2,000,000 contractual commitment to FhCMB under the Technology Transfer Agreement as described in Note 8. The Company has developed and could implement contingency plans to reduce its operation expense should circumstances require, though there can be no assurance that such plans will maintain adequate liquidity and prevent the possible impairment of assets.

The Company's historical operating results cannot be relied on to be an indicator of future performance, and management cannot predict whether the Company will achieve or sustain positive operating cash flows or generate net income in the future.

# Note 2. Summary of Significant Accounting Policies

Use of Estimates. The preparation of financial statements in conformity with generally accepted accounting principles 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. The most significant estimates include:

- Stock-based compensation;
- Valuation and recoverability of intangible assets, including the values assigned to acquired intangible assets;
- · Income taxes and valuation allowance on deferred income taxes, and;
- · Accruals for contingent liabilities, if any.

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.

**Revenue Recognition.** The Company recognizes revenue when the following four criteria under the Staff Accountant's Bulletin ("SAB 104") have been met: (i) persuasive evidence that an

arrangement exists, (ii) the product has been shipped or the service has been performed and the Company has no significant remaining obligation, (iii) the seller's price to the buyer is fixed or determinable and (iv) collectability is reasonably assured.

**Stock-Based Compensation.** The Company accounts for stock-based compensation in accordance with SFAS No. 123(R), share based payment. Under the fair value recognition provision, of this statement, share-based compensations cost is measured at the grant date based on the fair value of the award and is recognized as expense over the applicable vesting period of the stock award using the straight line method

Income Taxes. The Company accounts for income taxes using the liability method in accordance with the provisions of FASB Statement No. 109, "Accounting for Income taxes". 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 Per Share*. In accordance with FASB Statement No. 128, "Earnings Per Share," basic earnings per common share are based on weighted average number of common shares outstanding. Diluted earnings per share amounts are based on the weighted average number of common shares outstanding, plus the incremental shares that would have been outstanding upon the assumed exercise of all potentially dilutive stock options, warrants and convertible preferred stock, subject to anti-dilution limitations. For the fiscal years ended June 30, 2009 and 2008, the Company did not have any derivative securities outstanding which would result in the dilution of earnings per share.

Fair Value of Financial Instruments. Generally accepted accounting principles require disclosing the fair value of financial instruments to the extent practicable for financial instruments which are recognized or unrecognized in the balance sheet. The fair value of the financial instruments disclosed herein is not necessarily representative of the amount that could be realized or settled, nor does the fair value amount consider the tax consequences of realization or settlement. In assessing the fair value of financial instruments, the Company uses a variety of methods and assumptions, which are based on estimates of market conditions and risks existing at the time. For certain instruments, including cash, accounts receivable, notes receivable, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

*Intangible Assets.* Intangible assets consist of intellectual property and trademarks and patents. Amortization is being recorded on the straight-line basis over periods ranging from 10 years to 20 years based on contractual or estimated lives. The useful life of an intangible asset is the

period over which the asset is expected to contribute directly or indirectly to future cash flows. In accordance with the provisions of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the carrying value of intangible assets is evaluated whenever events or circumstances indicate that the carrying value may not be recoverable or at least on an annual basis. The carrying value is not recoverable when the projected undiscounted future cash flows are less than the carrying value. Tests for impairment or recoverability require significant management judgment, and future events affecting cash flows and market conditions could result in impairment losses. In the fiscal years ended June 30, 2009 and 2008, no impairment losses were indicated or recorded.

Contingent Liabilities. The Company records liabilities in accordance with the provisions of Statement of Financial Accounting Standards No. 5, "Accounting for Contingencies" when it is probable a liability has been incurred and the amount can re reasonably estimated or determined. In the fiscal years ended June 30, 2009 and 2008, no accruals or expenses for contingent liabilities were recorded.

# **Recent Accounting Pronouncements.**

In April 2008, the FASB issued FASB Staff Position (FSP) SFAS No. 142-3, "Determination of the Useful Life of Intangible Assets". FSP FAS No. 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets" and was effective for fiscal years beginning after December 15, 2008. The adoption of this pronouncement by the Company for the fiscal year ending June 30, 2010 will not have a material impact on the its financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ("SFAS 165"). SFAS 165 establishes general standards for accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or available to be issued and was effective for interim and annual periods ending after June 15, 2009. The adoption of SFAS No. 165 did not have an impact on the Company's results of operations or financial condition. The Company evaluated all subsequent events that occurred from July 1, 2009 through September 28, 2009, inclusive, and disclosed all material subsequent events in Note 11.

In June 2009, the FASB issued SFAS No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" ("SFAS No. 168"). SFAS No. 168 will become the single source of authoritative nongovernmental U.S. generally accepted accounting principles ("GAAP"), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force ("EITF"), and related accounting literature. SFAS No. 168 reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections. SFAS No. 168 will be effective for financial statements issued for reporting periods that end after September 15, 2009. The adoption of SFAS No. 168 is not expected to have a material impact on the Company's consolidated results of operations and financial condition.

# Note 3. Intangible Assets and Other Payables

The carrying amount of intangible assets as of June 30, 2009 and 2008 is as follows:

Intellectual property consists of exclusive licensing rights, patents and other technology relating to producing human health and veterinary influenza applications of the plant-based technology developed by the Center for Molecular Biotechnology of Fraunhofer USA, Inc. ("FhCMB").

Under a Technology Transfer Agreement (the "TTA") effective as of January 1, 2004, we acquired from FhCMB: (i) exclusive commercial rights to certain intellectual property invented and developed by FhCMB by which targeted proteins can be produced in plants for the development and manufacture of novel vaccines and therapeutics for humans and certain veterinary applications, and (ii) FhCMB's commitment for maintenance and support services necessary to further protect the Platform, including filing and prosecuting patent applications, providing scientific support for patent counsel's activities on behalf of the Company and otherwise to maintain in force and good standing the Company's intellectual property rights. The total contract price for the Platform and the support and maintenance services was \$3.0 million. In March 2006, and December 2007, the Company expanded the rights acquired from Fraunhofer to include veterinary and diagnostic applications of the Platform, for \$500,000 and \$100,000, respectively, which increased the original purchase price from \$3.0 million to \$3.6 million.

The Company recorded the payments under the TTA and payments to patent counsel for protection of the Platform as intangible assets with a definite life using the payments made to determine the fair value of the intellectual properties acquired. The Company recorded the payments at the due dates provided in the TTA after knowing that Fraunhofer had provided the required maintenance and support services in that period. When the parties entered into the TTA, we expected the articulation and filing of U.S. patent and other intellectual property protections to be accomplished substantially evenly over the term of the TTA. However, by June 30, 2007, when the Company determined that substantially all of the maintenance and support activities had been performed in support of the Platform because all of the patents and foreign applications contemplated to be filed to protect the Platform had been completed, the Company booked the remainder of the payments due under the TTA.

During the fiscal years ended June 30, 2009 and 2008, the Company made payments of \$1,050,000 and \$100,000, respectively, under an intellectual property acquisition agreement, as amended, with FhCMB entered into in January 2004. The Company remaining commitment of

\$1,050,000 as of June 30, 2008 is included in Other Payables. Amortization expense recorded on intangible assets for the fiscal years ended June 30, 2009 and 2008 was approximately \$280,000 and \$245,000, respectively. Amortization expense is recorded on the straight-line method over periods ranging from ten to twenty years and is included in selling and administrative expenses.

The estimated annual amortization expense for intangible assets for the five succeeding fiscal years is as follows as of June 30, 2009:

Fiscal year ending June 30,	
2010	\$315,000
2011	315,000
2012	315,000

 2013
 315,000

 2014
 2,075,000

\$3,650,000

#### Note 4. Due to Former Parent

Thereafter

Due to Former Parent consists of net cash advances from the Former Parent to assist the Company in meeting its obligations and for corporate support charges, offset by the Former Parent's use of the Company's federal net operating loss, see Note 5. The Former Parent did not charge the Company interest on any of these advances. These advances consisted of the following:

The corporate overhead allocation due our Former Parent were allocated based on the estimated time that the Former Parent's officers and employees dedicate to our Company's business and includes charges for employee salaries and benefits, legal, accounting and other consulting fees, treasury and tax services and general office expenses. The allocations were based on actual costs incurred by our Former Parent.

#### Note 5. Income Taxes

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial accounting purposes and the amounts used for income tax reporting. Significant components of the Company's deferred tax assets as of June 30, 2009 and 2008 follow:

Prior to the spin-off on August 12, 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 Integrated BioPharma 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 \$6.2 million and \$7.7 million are available to the Company and will expire at various times from 2010 through 2028. 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 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 consists of the following:

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

Effective July 1, 2007, the Company adopted FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN No. 48), which clarifies the accounting for uncertainty in income taxes recognized in the financial statement in accordance with FASB Statement No. 109 Accounting for Income Taxes. 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 on the Company's consolidated financial statements for the years ended June 30, 2009 and 2008.

Additionally, FIN No. 48 provides guidance on the recognition of interest and penalties related to income taxes. 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, 2009 and 2008.

The federal and state tax returns for the years ending June 30, 2008, 2007 and 2006 are currently open and the tax returns for the year ended June 30, 2009 are expected to be filed before December 31, 2009.

#### Note 6. Profit-Sharing Plan

The Company was included through August 12, 2008, the date of the spin-off, in Integrated BioPharma's profit-sharing plan, which qualifies under Section 401(k) of the Internal Revenue Code, covering all nonunion employees meeting age and service requirements. Contributions were determined by matching a percentage of employee contributions. The total expense for the fiscal years ended June 30, 2009 and 2008 was zero and approximately \$5,000, respectively.

# Note 7. Significant Risks and Uncertainties

- (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, 2009, the Company had uninsured cash balances totaling \$789,244.
- (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. The amount of the allowance for uncollectible accounts and other allowances as of June 30, 2009 and 2008 was zero and \$2,250, respectively. The Company's bad debt expense for the fiscal years ended June 30, 2009 and 2008 was zero and \$2,250, respectively.

(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 and 2008 approximated 49% and 92% 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 for one customer in connection with further development of plant-based technology. Accounts receivable from the latter represented 89% of the accounts receivable balance as of June 30, 2009. The Company does not expect revenues from any of these customers in the future.

- (d) Major Supplier and Related Party. The Company has subcontracted the manufacturing, including the oversight of its supply agreement with a wholly owned subsidiary of Integrated BioPharma (IHT Health Products, Inc. ("IHT")), who in turn contracts with another wholly owned subsidiary of Integrated BioPharma, substantially all of our cost of goods sold are paid to this related party. For the fiscal years ended June 30, 2009 and 2008, the Company was invoiced by IHT \$496,400 and \$484,500, respectively under this arrangement and such amounts are included in cost of goods sold in the accompanying statements of operations. The Company is not direct billed by the other related party utilized under the manufacturing arrangement.
- (e) Other Business Risks. The Company insures it 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.

# Note 8. Commitments and Contingencies

- (a) Leases. The Company leases office space on a month-to-month basis at the monthly rate of \$1,126. Total rent expense, including real estate taxes and maintenance charges, was approximately \$13,500 for each of the years ended June 30, 2009 and 2008.
- (b) Intellectual Property and Research Agreements. In connection with the acquisition in January 2004 of intellectual property developed by the Center for Molecular Biotechnology of Fraunhofer USA, Inc. ("FhCMB"), the Company entered into a Technology Transfer Agreement on December 18, 2003 (the "IP Agreement"), whereby the Company agreed to pay up to a maximum of \$3.0 million for certain technology developed by FhCMB over a five-year period. In addition to the IP Agreement, the Company entered into research agreements, which require

the payment of several milestone payments related to achieving certain flu vaccine studies and our ongoing Anthrax studies (the "R&D Agreements").

In March, 2006, the Company amended their IP Agreement with FhCMB to expand the scope of the IP Agreement and increased the amount of the purchase commitment to a maximum of \$3.5 million. In June 2007, the Company amended their existing amended IP Agreement and R&D Agreements with FhCMB, to commercialize the developed process, production techniques and methodologies of the proprietary technology and intellectual property for external applications. The June 2007 amendment requires FhCMB to continue to conduct research to enhance, improve and expand the existing intellectual property, and for this research the Company has committed to make non-refundable payments of \$2.0 million per year for five years, aggregating to \$10.0 million, beginning in November 2009. In addition, the Company will make royalty payments to FhCMB based on receipts derived by the Company from sales of products utilizing the proprietary technology for a period of fifteen years instead of the original the ten-year period. In turn, FhCMB shall pay the Company royalty payments for all receipts, if any, realized by FhCMB sales, licensing or commercialization of the intellectual property acquired by them for the same fifteen-year period. Furthermore, FhCMB has agreed to expend at a minimum, an additional \$2.0 million per year in the same timeframe as the Company for research and development on the intellectual property. A managing director of FhCMB is also a director on our Board and our Former Parent's Board of Directors.

In December 2007, the Company and FhCMB further amended the IP Agreement increasing the purchase price by \$100,000 to amend the field to include influenza diagnostics for an aggregate purchase price of \$3.6 million.

As of June 30, 2009, the Company has made payments in full for this purchase commitment of \$3.6 million.

(c) Disagreement Regarding Achievement of Milestone Under R&D Agreements. As of June 30, 2009 in connection with the R&D Agreements described in the previous section, FhCMB and the Company disagree regarding whether a certain technical milestone has been achieved by FhCMB which would trigger the obligation of a \$250,000 payment by the Company to FhCMB as of June 30, 2009. Management of both entities are working together to resolve this disagreement. If the Company recorded this obligation as of June 30, 2009, research and development expenses and the loss for the year ended June 30, 2009 would have increased by \$250,000 and accrued liabilities at June 30, 2009 would have increased by the same amount.

# Note 9. Equity Transactions

In November 2007, the Company entered into a Separation and Distribution Agreement (the "Distribution") with its Parent, whereby, the Former Parent agreed to distribute, pro rata, to the holders of its common stock, all of the shares of the Company's common stock owned by Integrated BioPharma. 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 our 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 our 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.

In August 2008, our Former Parent entered into a Conversion Agreement, whereby the Former Parent caused intercompany debt aggregating \$7,909,494 to be used as follows:

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

Subsequent to the Company's private placement as discussed below, our Former Parent owned 5.4% of the Company and that percentage ownership remains unchanged as of June 30, 2009.

Additionally, in August 2008, the Company closed on a \$5.0 million capital raise and received net proceeds of \$4,577,956 in connection with its private placement of approximately ten percent (10%) of the Company, such funds were released to the Company from the escrow and issued 2,345,752 shares of the Company's par value \$0.001 common stock, at an estimated purchase price of approximately \$2.13 per share. The Company also issued to the private placement investors, warrants to purchase a number of shares of common stock equal to 50% of the number of shares purchased by such private placement investor, with an exercise price equal to 150% of the purchase price of the Company's common stock subject to adjustments therein and warrants to purchase a number of shares of common stock equal to 50% of the number of shares purchased by such private placement investor, with an exercise price equal to 200% of the purchase price of the Company's common stock subject to adjustments therein and exercisable over the next five-year period. Proceeds from the issuance of these instruments were allocated to common stock and warrants based upon the relative amounts of the value of the notes and the estimated fair value of the warrants. The amounts allocated to warrants were accounted for through additional paid in capital.

#### Note 10. Stock-Based Compensation

In August 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.

The Company accounts for share-based compensation in accordance with Statement of Financial Accounting Standards No. 123(R), Share Based Payment ("FAS 123(R)"). Under the provisions of this statement, the Company measures the share-based compensation cost on the date of grant utilizing the fair value of the financial instrument(s) issued and recognizes such cost as an expense over the applicable vesting period of the award using the straight line method of amortization.

For the fiscal year ended June 30, 2009, the Company recorded stock-based compensation expense of \$13,059 in selling, general and administrative expenses which consisted of \$8,296 of expense related to options issued by the Company after the date of the spin-off from the Former Parent. Stock-based compensation expense in the fiscal years ended June 30, 2009 and 2008 included \$4,763 and \$55,945, respectively, allocated from our Former Parent for our employees and directors who received compensation in the form of stock options providing for the purchase of our Former Parent's stock upon vesting of their awards.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted average assumptions during the fiscal year ended June 30, 2009:

Risk-free 1.7% interest rate Dividend 0% vield Expected 80% volatility Expected term 4.3 years

(in years)

Forfeitures None

The risk-free interest rate is based upon observed interest rates appropriate for the expected term of the stock options. The dividend yield is zero as the Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The expected volatility is based on comparable companies as the Company has limited stock trading history as a publicly-held entity. The expected term is management's estimate of the period that the stock-based awards are expected to be outstanding. Forfeitures are assumed to be zero as the Company has a limited number of individuals participating in the Plan and operating history in its current form.

The weighted-average fair value of all options granted under the Plan during the fiscal year ended June 30, 2009 was \$0.13 per share.

The unrecognized share-based compensation cost related to non-vested options as of June 30, 2009 was \$91,000 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 4.3 years. The weighted-average remaining term of all options outstanding at June 30, 2009 was 4.3 years.

The following represents options outstanding for the period from August 12, 2008, the inception of the Plan, to June 30, 2009:

SFAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to the Company's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

# Note 11. Subsequent Events

In July 2009, the Company issued warrants to a financial advisor to purchase up to 100,000 shares of common stock. These warrants were fully vested upon issuance, expire in July, 2014 and have an exercise price of \$0.35 per share.

In August 2009, the Company issued options to Directors and Management to purchase up to 180,000 and 500,000 shares of common stock, respectively. These options vest ratably on the anniversary date of issuance over three and five year periods, respectively, expire August 10, 2014, and have an exercise price of \$0.66 per share.

In September 2009, the Company closed on a \$3 million private placement and issued 4,615,385 shares of common stock at \$0.65 per share and warrants for the purchase of 214,284 shares of common stock at a price of \$0.98 per share through September 10, 2014 and received net proceeds of \$2,833,000. The Company is obligated to file a registration statement within thirty days of the close of the private placement for the registration of those securities and use its best efforts to have such registration statement to be declared effective and to maintain that status.

# **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.

iBio, Inc.

Date: September 28, 2009 By: /s/ Robert B. Kay

Name: Robert B. Kay

Title: Chief Executive Officer

Date: September 28, 2009 By: /s/ Frederick Larcombe

Name: Frederick Larcombe Title: Chief Financial Officer

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