

iBioPharma, Inc.  
Form 10-K  
September 29, 2008

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

**FORM 10-K**

**Annual Report Under Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

For the fiscal year ended June 30, 2008 Commission File Number 000-53125  
**iBioPharma, Inc.**

*(Exact name of registrant as specified in its charter)*

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

26-2797813  
*(I.R.S. Employer Identification No.)*

9 Innovation Way, Suite 100, Newark, DE 19711  
*(Address of principal executive offices)*

19711  
*(Zip code)*

Registrant's telephone number: (302) 355-0650

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>                | <u>Name of Each Exchange on Which Registered</u> |
|---|--|
| Common Stock, \$0.001 par value per share | NONE   |

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

Yes | |                      No | 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 |

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

Yes  | No

Indicate by check mark 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" and "large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated Filer  |  
Accelerated Filer  |  
Non-accelerated Filer  |  
Smaller reporting company

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

Yes  | No

The aggregate market value of the voting stock held by non-affiliates of the Registrant based on the trading price of the Registrant's Common Stock on September 17, 2008 was \$17,510,063.

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

| <i>Class</i>                           | <i>Outstanding at September 18, 2008</i> |
|--|--|
| <u>Common Stock, \$0.001 par value</u> | <u>23,457,519 Shares</u>                 |

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.**



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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 iBioPharma, 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 changes in the Pharmaceutical manufacturing industry and Nutraceutical industry; 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”, “may”, “will”, “w”, “should”, “seeks”, or “scheduled to”, or other similar words, or the negative of these terms or other variations of these terms or comparable language, or by discussion of strategy or intentions. These cautionary statements are being made pursuant to the Securities Act, the Exchange Act and the PSLRA with the intention of obtaining the benefits of the “safe harbor” provisions of such laws. The Company cautions investors that any forward-looking statements made by the Company are not guarantees or indicative of future performance. Important assumptions and other important factors that could cause actual results to differ materially from those forward-looking statements with respect to the Company include, but are not limited to, the risks and uncertainties affecting their businesses described in Item 1A of this Annual Report on Form 10-K and in other securities filings by the Company.

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



## PART I

### Item 1. Description of Business

#### Overview

iBioPharma, Inc., a Delaware corporation, (formerly InB:Biotechnologies, Inc., a New Jersey corporation) (the “Company”) is a biopharmaceutical company focused on using and promoting the use of our proprietary plant-based technology platform (which we refer to herein as the platform or our platform) by which targeted proteins can be produced in plants for the development and manufacture of novel vaccines and therapeutics for use in humans and for certain veterinary applications.

This 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 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.

Our business model contemplates that, in addition to using our platform to create and advance our own product candidates, we will license the platform to, or enter into joint ventures or other business arrangements with, other parties (collectively, we refer to these third parties as licensees) who wish to use the platform for the development and/or production of their own product candidates. In order to attract appropriate licensees and increase the value of the Company’s share of such 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 flu vaccine for human use as the product candidate to exemplify the value of the platform particularly for products that require rapid, highly-scalable and economic production. Performance of this first research agreement, which requires us to make payments to FhCMB against the achievement of stated research milestones, has progressed through preclinical challenge studies in the ferret model. Clinical trials are expected to begin in the second quarter of 2009.

In addition, 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. Fabricated equipment for the prototype is scheduled to be delivered to FhCMB by November 2008. Equipment in the facility is scheduled to be commissioned and the facility validated for current Good Manufacturing Practices (called cGMP) production in the first quarter of 2009. The facility will then be used for pilot scale production of protein targets for clinical trials of product candidates which use our platform technology.

In addition to our direct funding of FhCMB’s application of the platform technology to our human flu vaccine product candidate, 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, 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 enables us to obtain commercial rights to various applications



of our platform technology funded by government entities and NGOs. 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. Our use of FhCMB to perform 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.

Using this business structure, we have applied our platform technology to create a pipeline of proprietary product candidates which we can offer to licensees, including vaccine and therapeutic candidates against seasonal and pandemic influenza, human papilloma virus (HPV), and other pathogens of public health significance. All of our product candidates are in the preclinical development stage, and to date, none of our product candidates has been approved by the FDA.

We have exclusive control over and the rights to ownership of the intellectual property related to 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 and HPV vaccines and antibodies for potential treatment and diagnosis of influenza infections.

Biotech drugs are proteins such as antibodies, blood proteins and enzymes. 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 due to 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, we have also used plants as sources of high-quality nutritional supplements. 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. Following the spin-off, we will continue to engage the services of various wholly-owned subsidiaries of Integrated BioPharma, Inc., (“Integrated BioPharma” or “Parent”) formerly our parent company, for the production, marketing and sales of these phytomineral products.

### **Our Business Structure**

A key element of our business strategy and our thinly-staffed employment structure is to establish business arrangements with licensees, particularly leading pharmaceutical and biotechnology companies, to use our platform technology for the development and commercialization of our product candidates. 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. This is currently our only similar business relationship. The termination of this arrangement might adversely affect our ability to develop and commercialize our product candidates.

We rely 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. Our possible 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 customers 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 vaccine or other product candidates, therefore, may be subject to competition with a product candidate under development by a licensee or customer.

We are pursuing and obtaining non-dilutive government and non-governmental organization funding directed through FhCMB to provide supplemental capital for advancement of our programs. To date, FhCMB has been awarded a total of \$7.7 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). To facilitate the grant and continuing support, we have agreed to make our platform technology available to various programs to complete development and provide so-called “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 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 technology that we may decide to commercially license to advance into human clinical evaluation and eventual commercial development. The U.S. Department of Defense (“DoD”) has also provided \$14.4 million in funding to FhCMB for preclinical and clinical studies for the anthrax and plague vaccine projects, and this funding is similarly beneficial to us because of our rights to commercially exploit the technology developed.

Pursuant to the Technology Transfer Agreement between the Company and FhCMB, effective as of January 1, 2004, we agreed to make payments totaling \$3,600,000 to FhCMB on a non-contingent basis for the acquisition of 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, of which one United States patent has been granted, one allowed, and 21 are pending. In addition 34 foreign patent applications are pending.

The 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 and HPV. As of March 1, 2006, we amended this agreement to include veterinary influenza applications.

In addition to the acquisitions pursuant to the Technology Transfer Agreement, the Company has by separate agreements in the ordinary course engaged FhCMB to perform certain research activities for which the Company makes payments when certain milestone tasks have been performed. The payments are conditioned only on the performance of the task, not upon the success or value of what is determined or discovered.

We amended our agreements with FhCMB to extend our licensing rights from 10 years to 15 years concurrent with the additional commitment to provide funding to commercialize the developed process, production techniques and methodologies of the proprietary technology and intellectual property for external applications. This amendment also requires FhCMB 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 November 2009. In addition, the Company will 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 shall pay the Company royalty payments equal to 9% of all receipts, if any, realized by FhCMB sales, licensing or commercialization of the intellectual property acquired.

iBioPharma is a direct participant with FhCMB on a contract from DARPA (Defense Advanced Research Agency) of the United States Department of Defense for an \$8.5 million project to further develop our plant-based technology platform for accelerated manufacture of vaccines and antibodies. The sub-contract is for an aggregate of \$1.035 million over a 27-month period which began in May 2007. Phase 1 of the sub-contract was awarded and is complete (\$90,000). We expect Phase 2 of the contract (\$945,000) to be awarded in October 2008. The contract will facilitate construction of a pilot manufacturing plant using our platform technology with capacity to provide sufficient materials for clinical trials.

We are also a party to a Non-Standard Navy Cooperative Research and Development Agreement, or CRADA, dated September 10, 2004, along with Naval Medical Research Center, or NMRC, and FhCMB, pursuant to which the parties agreed to collaborate in the evaluation of an anthrax vaccine for its capacity to boost pathogen-specific immune responses in individuals vaccinated against anthrax upon non-invasive oral administration. Pursuant to the CRADA, each party agrees to retain ownership of any data, copyright, trademark or patent produced by that party. However, FhCMB agreed to transfer certain patents produced pursuant to the CRADA to us, and in return we agreed

to pay FhCMB up to \$100,000 for its efforts upon the meeting of various milestones. Additionally, NMRC agreed to fund its own efforts associated with the CRADA. The CRADA expired by its terms on August 30, 2005, but the parties are continuing their working relationship under the agreement.





## Our Product Candidates

Our short-term focus is to demonstrate the commercial value of our platform technology through its application to vaccines and therapeutics for influenza and human papilloma virus (HPV). 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. None of our product candidates have entered human clinical testing, and all of them are at a preclinical stage of development. We estimate that none of our product candidates will enter human clinical testing before the second quarter of 2009.

Diagnostic Product for Pandemic Avian Influenza. While predicting the timing of an avian influenza pandemic is not possible, reducing the potentially devastating impact of an outbreak requires an efficient method to distinguish avian influenza infections from other respiratory diseases, including seasonal influenza. There currently are no rapid diagnostic tests available for this purpose. FhCMB has discovered an antibody that appears to distinguish highly pathogenic avian influenza strains (total of 19 strains from clades (“clade” is the technical term for category) 1, 2a and 2b) from human seasonal influenza viruses. We plan to develop this proprietary antibody with a commercial partner as a point of care diagnostic product. We do not currently have a commercial partner for this product candidate.

Seasonal Influenza Vaccine. We are developing 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 a recent study, we evaluated 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.

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 on 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 Influenza Vaccine. We are developing vaccine candidates targeting highly pathogenic avian influenza (H5N1) viruses. 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 long term goal is to develop a combined vaccine effective for preventing both seasonal and pandemic influenza infections.

Therapeutic Antibody for Influenza. Our prototype product for treatment of patients hospitalized with avian influenza is an antibody that specifically inhibits neuraminidase activity of highly pathogenic avian influenza virus strains from clades 1 and 2. Antibodies are proteins that bind specific targets, and neuraminidase is a viral protein necessary for the spread of influenza virus. When an antibody binds neuraminidase tightly enough, it can block the function of neuraminidase and stop the spread of the virus. We have preclinical evidence that the antibody is effective against drug-resistant virus samples. This antibody has potential for prophylactic use and as a first line therapy in a flu

pandemic. This antibody is in the preclinical development stage.



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.

Biodefense Products. We have commercial rights to an oral anthrax booster vaccine candidate developed by FhCMB in collaboration with the Naval Medical Research Center (NMRC). Animal tests have demonstrated safety and efficacy of this product candidate. We also have commercial rights to candidate plague vaccines that FhCMB has demonstrated to be effective in non-human primate tests in which four groups of two monkeys each were inoculated and then challenged with plague infection. Detailed results of these experiments were published in 2007 in the scientific journal *Vaccine*, 2007 Apr 20; 25(16):3014-7.

Under DoD sponsorship, FhCMB is also conducting 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 are dependent on FhCMB to conduct experiments to further develop these products.

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

## **Target Markets**

We believe that our platform technology is well-suited for application to both vaccines and antibodies. Both vaccines and antibodies are well established in clinical practice, and the route to regulatory approval for product marketing is clear for both categories based on guidance documents issued by the FDA and available at the FDA's website, [www.fda.gov](http://www.fda.gov). We have focused our expertise in these product classes for 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).

Influenza Market. 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 development of an antibody for treatment of avian influenza. We believe that market demand for influenza vaccines and therapeutics is growing quickly, driven by the increasing pandemic threat, broader target populations who are medically recommended to be vaccinated and increased compliance by the target populations to receive vaccines. 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 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 will be able to address such a critical need. We have demonstrated the efficiencies of this technology at a laboratory level by producing candidate influenza vaccines in weeks versus the months required for commercially-used chicken egg

methods. The yields we have obtained in these laboratory experiments are high enough to be competitive with other methods if we can achieve the same yields and the same time efficiencies on a commercial scale. We, however, have not yet tested our technology at the scale that will be required for commercial use, nor at a scale sufficient to conclude what our commercial cost of goods will be.



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

**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.

Our iBioLaunch technology consists of compositions and processes that enable growing green plants to make proteins they do not naturally make, and for these new proteins to be made fast enough and in high enough yields to facilitate the evaluation of new product candidates. 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.

| Target | Produced via iBioLaunch | <i>In vitro</i> characterization complete | Immunogenicity demonstrated in animal model | Efficacy demonstrated in animal model |
|--------|-------------------------|---|---|---------------------------------------|
|--------|-------------------------|---|---|---------------------------------------|

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|                     |   |   |   |   |
|---------------------|---|---|---|---|
| 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<br>(therapeutic/diagnostic) | X | X | NA | UT |
| Anthrax antibody (therapeutic)                 | X | X | NA | X  |
| Tetanus toxin antibody<br>(therapeutic)        | X | X | NA | UT |
| hGH (therapeutic)                              | X | X | NA | UT |
| GM-CSF (therapeutic)                           | X | X | NA | UT |
| Diabetes autoantigen<br>(diagnostic)           | X | X | NA | UT |

NA = not applicable UT = untested

We currently are prioritizing the following product candidates for our in-house research and development portfolio:

| <b>Product</b>       | <b>Indication</b>               | <b>Current status</b> |
|----------------------|---------------------------------|-----------------------|
| Subunit vaccine      | Seasonal and Pandemic influenza | Preclinical           |
| Subunit vaccine      | Human Papilloma Virus Therapy   | Preclinical           |
| Antibody             | Influenza                       | Preclinical           |
| Oral booster vaccine | Anthrax                         | Preclinical           |
| Multivalent vaccine  | Anthrax and plague              | Preclinical           |
| Antibody             | Anthrax                         | Preclinical           |

**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 one issued U.S. patent for inducing gene silencing in plants that expires on July 25, 2022 and one U.S. patent application describing systems for expression of vaccine antigens in plants for which we have received a notice of allowance. We have an additional 21 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 34 pending foreign patent applications.



The following summarizes the issued and pending patent applications on our technology and products:

Issued Technology Filing (U.S.)

- Virus-induced gene silencing in plants

Pending Technology Filings (U.S. and International)

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

Pending Product Filings (U.S. and International)

- Antibodies
- Influenza vaccines
- Influenza therapeutic antibodies
- Anthrax vaccines
- Plague vaccine

- HPV  
vaccines
- Trypanosomiasis  
vaccine
- Diabetes  
autoantigen
- Human  
growth  
hormone

### **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 2 or equivalent human clinical data before negotiating license or marketing agreements. 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 have no experience in the sales, marketing and distribution of pharmaceutical products. 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 influenza vaccine business. 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 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 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.

Clinical trials are typically conducted in three sequential phases, Phases 1, 2 and 3, with Phase 4 trials potentially conducted after initial marketing approval. The phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase 1.* After an IND becomes effective, Phase 1 human clinical trials may begin. These trials evaluate a product’s safety profile and the range of safe dosages that can be administered to healthy volunteers and/or patients, including, in some cases, the maximum tolerated dose that can be given to a trial subject with the target disease or condition. Phase 1 trials of drug candidates also determine how a drug is absorbed, distributed, metabolized and excreted by the body and the duration of its action. In the case of vaccines, human subjects are monitored for desirable immune reactions and for undesirable side effects.
- *Phase 2.* Phase 2 clinical trials are typically designed to evaluate the potential effectiveness of the product in patients and to further ascertain the safety of the drug at the dosage given in a larger patient population. In the case of vaccine candidates, these tests are expected to demonstrate efficacy within the statistical limitations of the relatively small Phase 2 clinical trial study population, and further reduce concern that the product candidate may induce unwanted side effects.

- *Phase 3.* In Phase 3 clinical trials, the product is usually tested in one or more controlled, randomized trials comparing the investigational new drug or vaccine to an approved form of therapy or vaccination or placebo in an expanded and well defined patient population and at multiple clinical sites. The goal of these trials is to obtain definitive statistical evidence of safety and effectiveness of the investigational new drug regimen or vaccine formulation as compared to a placebo or an



- approved standard therapy or vaccine in defined patient populations with a given disease and stage of illness, or exposed to a specific disease-causing agent such as a virus or bacterium.
- *Phase 4.* Clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. These clinical trials are often referred to as Phase 3/4 post approval clinical trials. Failure to promptly conduct Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

After completion of Phase 1, 2 and 3 clinical trials, if there is substantial evidence that the drug or vaccine is safe and effective, a BLA is prepared and submitted for the FDA to review. We are not developing drugs as that term is defined by the FDA, and, therefore, if we successfully complete Phase 3 clinical trials, we would file a BLA for our vaccine or biologic candidate product. The BLA must contain all of the essential information on the product gathered to that date, including data from preclinical and clinical trials, and the content and format of a BLA must conform to all FDA regulations and guidelines. Accordingly, the preparation and submission of a BLA is a significant undertaking for a company.

A vaccine product for prevention of seasonal influenza must be modified frequently, usually each year, as the dominant strains of influenza virus change from season to season. Because these products must be modified so often, the regulations for their approval for marketing differ from biologic products that are not changed so frequently. FDA requirements specific to seasonal influenza vaccine products are described in the FDA document entitled “Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines.” Although we plan to develop subunit vaccines for seasonal influenza rather than inactivated virus vaccines, the safety and efficacy standards of the FDA will not be less stringent than those described in the cited guidance document.

In the case of a vaccine candidate intended to be used in the event of a pandemic influenza outbreak, the requirements for regulatory approval do not include a Phase 3 clinical trial. This is because it is not ethical to subject human subjects to infection with a disease agent they would not naturally be exposed to, such as a hypothetical avian influenza strain with pandemic potential. Therefore, a vaccine candidate for this use must undergo rigorous evaluation of safety in Phase 1 and Phase 2 clinical trials, but efficacy is measured by evaluating subjects’ immune responses rather than by assessing the effectiveness of the vaccine candidate in actually preventing disease. The details of the requirements for FDA approval of a vaccine candidate such as our potential vaccine for pandemic influenza are available in the FDA publication “FDA Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines.” A PDF copy of this publication can be downloaded from the FDA website at <http://www.fda.gov/cber/gdlns/panfluvac.htm>.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information from the sponsor rather than accepting an application for filing. In this case, the application must be re-submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Most applications are reviewed by the FDA within 10 months of submission. The review process is often significantly extended by the FDA through requests for additional information and clarification. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation but typically gives it great weight. If the FDA evaluations of both the

BLA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, the latter of which usually contains a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the BLA submission or manufacturing facility is not favorable, the FDA may refuse to approve the application or issue a not approvable letter.

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.

Vaccine candidates that are intended for therapeutic use, such as our candidate for treatment of HPV, must also undergo rigorous safety evaluation. Once we have satisfied FDA requirements for initial demonstration of safety, we must then prove that the vaccine candidate is capable of inducing an immune response in humans that is specific to the disease target and strong enough to be likely to provide a treatment benefit. The vaccine candidate must then be tested successfully in human volunteers with the condition to be treated, and we must demonstrate statistically significant improvements in clinical symptoms in patients who receive our experimental vaccine versus those who receive standard care or a placebo in the absence of a standard treatment.

There may be uncertainty regarding regulatory requirements for developing and obtaining marketing approval for an antibody expected to treat avian influenza infections. A product such as this may be regulated similarly to an avian influenza vaccine candidate, however the animal testing requirements will probably be much more substantial and costly due to the potential safety issues associated with the higher systemic doses of antibody required to achieve a therapeutic benefit versus the lower doses of a vaccine required to achieve a protective immune response.

### **Product Liability**

Our business involves exposure to potential product liability risks that are inherent in the production and manufacture of pharmaceutical products. Prior to the Spin-off, we maintained product liability insurance until 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 will continue to be covered under Integrated BioPharma's product liability policy since the manufacturing process is performed by wholly owned subsidiaries of Integrated BioPharma. 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 18, 2008, we had eight 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 to increase our number of employees to ten during the next 12 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 [www.ibiopharma.com](http://www.ibiopharma.com). You may request a copy of our filings with the SEC (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

iBioPharma, 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.
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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 \$5.0 million private placement of common stock that closed in August 2008, as described herein, and support from FhCMB collaborators, will be sufficient to meet our projected operating requirements only through the second calendar quarter 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.

We estimate we would need to raise additional funds of approximately \$35 million over the next three years to operate our business and independently fund a Phase 3 clinical trial of one of our product candidates. Our funding needs would likewise increase as we move additional product candidates through the clinical trial process.

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. For example, large pharmaceutical companies are in the influenza vaccine business. 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, these large companies would be our competitors.

Smaller or early stage companies may also prove to be significant competitors, particularly through business arrangements with large and established companies that may reduce the potential demand for access to our platform. For example, Novavax is conducting human clinical trials of vaccines for influenza and other infectious diseases using cell culture processes for manufacturing, and Medicago has announced preclinical experiments to produce influenza vaccines in green plants.

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 and our thinly-staffed employment structure is to establish arrangements with licensees, particularly leading pharmaceutical and biotechnology companies, 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:





- 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 biopharmaceutical companies like us are highly uncertain and involve complex legal and factual questions. To date, we have 22 U.S. applications pending and 34 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.

### **Risks Relating to Our Relationship with and Spin-Off from Integrated BioPharma**

*Our business could suffer if our systems and infrastructure are inadequate or we cannot replace the other benefits previously provided by Integrated BioPharma.*

Since our inception, we have relied on Integrated BioPharma for various services which we have only recently developed for ourselves, including:

- legal;
- treasury;
- tax;
- employee benefits;
- insurance;
- investor relations;

and

- executive oversight and other services

As of August 18, 2008, following the distribution, we are operating as a separate publicly traded company. We have developed and implemented systems and infrastructure to support our current and future business, and our responsibilities as a public company. These systems and infrastructure may be inadequate, however, and we may be required to develop or otherwise acquire other systems and infrastructure, or to obtain certain corporate services from Integrated BioPharma to support our current and future business such as legal, strategic financial planning, tax and





SEC reporting services. For further detail, please see “Relationship Between Our Company and Integrated BioPharma, Inc. – Agreements Between Us and Integrated BioPharma.”

***As of August 18, 2008, subsequent to the distribution from Integrated BioPharma, we are not able to obtain financing from Integrated BioPharma.***

Our plans to expand our business and to continue to improve our products may require funds in excess of our cash flow and will 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. As of August 18, 2008, subsequent to the distribution, however, Integrated BioPharma is not providing funds to finance our operations. Without the opportunity to obtain financing from Integrated BioPharma, we will need to obtain additional financing from banks, or through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements. We cannot give assurances at this time that we will be able to obtain such funding. In addition, 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 reduce our profitability. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.”

***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.

#### **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. We expect to expand our leased office space to approximately 1,500 square feet during the next 12 months, and we believe this space will be adequate to perform the same 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, 2008.



## PART II

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

#### Market Information

On August 18, 2008, after the Company's most recent fiscal year, the Company's common stock commenced trading on the OTC Bulletin Board under the symbol "IBPM.OB".

#### Holdings

As of June 30, 2008, the Company was a wholly owned subsidiary of Integrated BioPharma, Inc. On the distribution date of August 18, 2008, from Integrated BioPharma, 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 or 2007 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

None

### 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

iBioPharma, Inc. (formerly, InB:Biotechnologies, Inc.) (the "Company") is a biopharmaceutical company focused on using and promoting the use of its proprietary plant-based technology platform (the "Platform") 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. References in this Annual Report, on Form 10-K, to "we," "us", "our company" or "InB:Biotechnologies", refer to iBioPharma, Inc.. The 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 from FhCMB the Platform and FhCMB’s commitment for 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.

Our business model contemplates that we will license the Platform to, or enter into joint ventures or other collaborative arrangements (collectively, "Licenses") with, other parties ("Licensees") who wish to use the Platform for the development and/or production of their own product candidates. In order to attract appropriate Licensees and increase the value of the Company's share of such collaborative arrangements, the Company engaged FhCMB in October 2004, to perform research and development activities to apply the Platform to create a product candidate. The Company selected plant-based flu vaccine for human use as the product candidate to exemplify the value of the Platform particularly for products that require rapid, highly-scalable and economic production. Performance of this first research agreement, which requires us to make payments to FhCMB against the achievement of stated research milestones, has progressed through preclinical challenge studies in the ferret model. Clinical trials are expected to begin in the second quarter of 2009.

In addition, 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 Licensees and increase the value of the Company's share of collaborative 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. Fabricated equipment for the prototype is scheduled to be delivered to FhCMB by November 2008. Equipment in the facility is scheduled to be commissioned and the facility validated for cGMP production in the first quarter of 2009. The facility will then be used for pilot scale production of protein targets for clinical trials of product candidates which use our Platform technology.

In addition to our direct funding of FhCMB's application of the Platform technology to our human flu vaccine product candidate, we have established arrangements ("Non-Commercial Arrangements") among the Company, certain government entities ("GEs"), a non-governmental organization ("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 GEs and NGO, in consideration for grants by the GEs and NGO directly to FhCMB to fund such research and development.

Through the Company/FhCMB contracts and the Non-Commercial Arrangements (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; but licenses or otherwise grants use rights (i) to GEs and NGO entities for not-for-profit applications of the intellectual property for the development or application of which they granted funding, and (ii) to FhCMB for research purposes and applications in other fields. This Business Structure is enabling us to obtain commercial rights to various applications of our Platform technology funded by GEs and NGOs. It also helps us demonstrate the validity and apparent value of the Platform to parties to whom we will offer licenses or collaborative opportunities. Our use of FhCMB to perform research and development work allows us to develop our product candidates, and thereby promote the value of our Platform for licensing and collaboration purposes, without bearing the full risk and expense of establishing and maintaining our own research and development staff and facilities.

Using this Business Structure, we have applied our Platform technology to create a pipeline of proprietary product candidates which we can offer to Licensees, including vaccine and therapeutic candidates against seasonal and

pandemic influenza, human papilloma virus (HPV), and other pathogens of public health significance. All of our product candidates are in the preclinical development stage. We sometimes refer to the Platform technology as “iBioLaunch™ technology” or the “iBioLaunch™ platform,” and we refer to the category of this technology as “plant-based technology” or as a “plant-based platform.”



Historically, we have also used plants as sources of high quality nutritional supplements. 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. Following the spin-off, we will continue to engage the services of various wholly-owned subsidiaries of Integrated BioPharma for production, marketing and sales of these phytomineral products.

In the fiscal year ended June 30, 2008, our operating expenses increased to \$2.4 million or approximately 14% from \$2.1 million for the fiscal year ended June 30, 2007. The significant increase was primarily due to increases in salary and benefits of approximately \$200,000 as a result of the Company hiring its own staff, the number of employees increased from one in the fiscal year ended June 30, 2007 to five in the fiscal year ended June 30, 2008, including the addition of our president in October 2007. Another contributing factor to the Company's increased expenses was a result of the loss on an investment of \$253,500. In December 2006, the Company made an investment in a private biotech company that was in its initial stages of filing to become a public company. In the three month period ended December 31, 2007, the Company, based in part on information from public filings filed in February 2008 by this biotech company, which stated that if the company was unsuccessful in its efforts to raise additional capital, it only had enough cash on hand to cover operating expenses through May 2008 and if it were successful in obtaining additional funding, such financings would have a dilutive effect to current stockholders. Furthermore, this biotech company is not a public company, the financial statements included in the public filing stated that there was substantial doubt about the company's ability to continue as a going concern and there is no established market for the investment we hold, we therefore recorded a valuation reserve equal to our entire investment of \$253,500, in this biotech company. These increases were offset by a decrease in research and development costs of \$123,000.

For the fiscal year ended June 30, 2007, our operating expenses increased to \$2.1 million or approximately 45% from \$1.5 million for the fiscal year ended June 30, 2006. The significant increases were in both our research and development costs, and amortization expense, approximately \$244,000 and \$160,000, respectively as we continued to develop applications that use our intellectual property, expand our patent portfolio and achieve significant milestones under our Research Agreements with FhCMB.

#### **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. However, due to several relationships between the two companies that existed prior to the distribution, we have or will enter into one or more agreements regarding the effects of the distribution and ongoing business relationships under our supply agreement with Mannatech, Inc. ("Mannatech"), whereby, we engage the services of other wholly-owned subsidiaries of Integrated BioPharma. It is expected that our cost of goods sold under this agreement will increase from an average of 50% to 90%. As of January 1, 2008, an employee of ours was transferred to the payroll of one of the wholly owned subsidiaries of Integrated BioPharma, and this cost will be transferred from operating expenses to cost of goods sold as a result of this change in business arrangement.

#### **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:

- sales returns and allowances;



- allowance for doubtful accounts;
- valuation and recoverability of intangible assets, including the values assigned to acquired intangible assets;
- income taxes and valuation allowances on deferred income taxes; and
- accruals for, and the probability of, the outcome of litigation, 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.

#### ***Allowances for Doubtful Accounts and Sales Returns***

The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding amounts. We continuously monitor payments from our customers and maintain allowances for doubtful accounts for estimated losses in the period they become known.

We performed a sensitivity analysis to determine the impact of fluctuations in our estimates for our allowance for doubtful accounts. As of June 30, 2008, we had an allowance for doubtful accounts of approximately \$2,300, as we believe that we have minimal exposure that our customers will not pay for their outstanding receivables as of June 30, 2008. If we were in error by one percent of the account receivable balance, the impact would be \$1,100 of expense. In recording any additional allowances, a respective charge against income is reflected in the general and administrative expenses and would reduce the operating results in the period in which the increase is recorded.

The Company's return policy is to only accept returns for defective products. If defective products are returned, it is the Company's agreement with its customers that the Company cure the defect and reship the product. Our policy is that when the product is shipped we make an estimate of any potential returns or allowances. As of June 30, 2008, we had estimated that a no reserve was needed as an allowance for potential returns or allowances of our sales for the fiscal year ended June 30, 2008. If we were in error by plus or minus one percent of the sales for this period, the impact would be approximately \$9,900 of additional income or expense. In recording any additional allowances, a respective charge against income is reflected in sales, net and would reduce the operating results in the period in which the increase is recorded.

#### ***Intangible Assets***

The Financial Accounting Standards Board ("FASB") has issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 142 requires that goodwill and intangible assets with indefinite lives no longer be amortized against earnings, but instead tested for impairment at least annually based on a



fair-value approach as described in SFAS 142.

Intangible assets with finite lives are amortized over their estimated useful 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. The carrying value of intangible assets with finite lives is evaluated whenever events or circumstances indicate that the carrying value may not be recoverable. 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.

If our estimated useful lives on our intangible assets are off by 10%, either the estimated useful lives should be longer or shorter than their current estimated lives, our amortization expense would be approximately \$27,400 more on a per annum basis if the estimate useful lives should be shorter by 10% than our current estimates and approximately \$22,100, per annum, less if the estimated useful lives should be longer by 10% of our current estimates.



### ***Deferred Taxes***

The Company accounts for income taxes pursuant to SFAS No. 109, "Accounting for Income Taxes" (SFAS 109"). SFAS 109 is an asset-and-liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences and events that have been recognized in the Company's financial statements or tax returns. In the fiscal year ended June 30, 2008, the Company had net income tax expense of approximately \$4,000 compared to approximately \$1,000 in the fiscal year ended June 30, 2007. Our ability to recognize an income tax benefit has been dependent on the consolidated federal taxable income (loss) of Integrated BioPharma's controlled group for federal income tax purposes. In the fiscal year ended June 30, 2008 and 2007, the controlled group of Integrated BioPharma had a taxable losses and, therefore, did not utilize any of the losses generated by us and as a stand alone taxable entity, we would have to reserve 100% of our resulting deferred tax asset generated from the net operating loss as it is more likely than not that, in the near term, we will not generate sufficient taxable income to offset our Fiscal 2008 taxable loss. Our deferred tax asset 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 we will not have sufficient taxable income in the near future to offset any income taxes resulting from taxable income. Since we expect that we will continue to have future losses, we do not expect to have to pay any federal income taxes and pay only any minimum taxes in the states we operate in.

### ***General Litigation***

From time to time, the Company could be a defendant or plaintiff in various legal actions which arise in the normal course of business. As such, we would be required to assess the likelihood of any adverse outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of the provision required for these commitments and contingencies, if any, which would be charged to earnings, would be made after careful analysis of each matter. Any resulting provision may change in subsequent periods due to new developments or changes in circumstances. Changes in the provision could increase or decrease the Company's earnings in the period the changes are made.

### ***General***

The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin 104. The Company recognizes product sales revenue, the prices of which are fixed and determinable, when title and risk of loss have transferred to the customer, when estimated provisions for product returns, charge-backs and other sales allowances are reasonably determinable, and when collectibility is reasonably assured. Accruals for these items are presented in the financial statements as reductions to sales. The Company's net sales represent gross sales invoiced to customers, less certain related charges for discounts, returns and other allowances. Cost of sales includes the cost of raw materials and overhead associated with the packaging of the products.

### ***Recent Accounting Pronouncements***

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities", an amendment of FASB SFAS No. 133. SFAS No. 161 requires disclosure of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008, with early adoption permitted. We do not expect SFAS No. 161 to have a material impact on our consolidated financial position, results of operations and cash flows.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in financial statements," an amendment

of ARB No. 51. The standard changes the accounting for noncontrolling (minority) interests in financial statements including the requirements to classify noncontrolling interests as a component of consolidated stockholders' equity, and the elimination of "minority interest" accounting in results of



operations with earnings attributable to noncontrolling interests reported as a part of consolidated earnings. Additionally, SFAS No. 160 revises the accounting for both increases and decreases in a parent's controlling ownership interest. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. We are currently evaluating the impact of the pending adoption of SFAS No. 160 on our financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB SFAS No. 115," which allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for certain financial assets and liabilities on an instrument-by-instrument basis. Subsequent measurements for the financial assets and liabilities an entity elects to record at fair value will be recognized in earnings. SFAS No. 159 also establishes additional disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, with early adoption permitted provided that the entity also adopts SFAS No. 157. The adoption of SFAS No. 159 did not have a material impact on our financial position, results of operations and cash flows.

In September 2006, the FASB issue SFAS No. 157, "Fair Value Measurement" ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 17, 2007. In February 2008, the FASB issued FASB Staff Position No. 157-1, "Application of FASB SFAS No. 157 to FASB SFAS No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13 and FASB Staff Position No. SFAS 157-2, Effective Date of SFAS No. 157." Collectively, the Staff Positions defer the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, for nonfinancial assets and nonfinancial liabilities except for items that are recognized or disclosed at fair value on a recurring basis at least annually, and amend the scope of SFAS No. 157. We are currently evaluating the impact of the pending adoption of SFAS No. 157 on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations." The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition related restructuring liabilities, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited.

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." FSP SFAS No. 142-3 is effective for fiscal years beginning after December 15, 2008 and early adoption is prohibited. We are currently evaluating the impact of the pending adoption of FSP SFAS No. 142-3 on our financial statements.

In June 2007, the FASB ratified EITF No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities: (EITF No. 07-3). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 will not have a material impact on our financial statements.

## Results of Operations

**Fiscal year ended June 30, 2008 compared to the fiscal year ended June 30, 2007**

30





**Net Sales.** Net sales for the fiscal year ended June 30, 2008 and 2007 were \$987,100 and \$896,300, respectively, an increase of \$90,800 or 10%. Sales under our supply agreement with Mannatech represent substantially all our net sales in both periods.

For the fiscal year ended June 30, 2008, approximately 92% of net sales were derived from two customers. These two customers, JB Laboratories, Inc and Natural Alternatives International, 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. For the fiscal year ended June 30, 2007, substantially all of our net sales (98.6%) were derived from three customers: Mannatech (60.3%), Natural Alternatives International (21.4%) and JB Laboratories, Inc. (16.9%), all in connection with our supply agreement with Mannatech. The loss of any of these customers would have an adverse affect on the Company's operations.

**Cost of sales.** Cost of sales increased to \$485,100 for the fiscal year ended June 30, 2008, as compared to \$445,700 for the fiscal year ended June 30, 2007. Cost of sales, as a percentage of sales, were 49.1% and 49.7%, respectively for the fiscal years ended June 30, 2008 and 2007.

**Research and Development Costs.** Our research and development costs were \$550,000 in the fiscal year ended June 30, 2008 compared to \$673,200 in the fiscal year ended June 30, 2007. Research and development costs consist primarily of payments made or owed to FhCMB in reaching milestones under our research agreements with them. The decrease of approximately \$123,200 was primarily the result in a decrease of \$100,000 of payments made to FhCMB under our research agreements with them and the lack of \$23,200 payments made under a research project separate from our FhCMB relationship in the fiscal year ended June 30, 2008 compared to the fiscal year ended June 30, 2007.

**Selling and Administrative Expenses.** Selling and administrative expenses were \$1,817,500 for the fiscal year ended June 30, 2008, an increase of \$375,000 or 26% as compared with \$1,442,500 for the fiscal year ended June 30, 2007. A tabular presentation of the changes in selling and administrative expenses is as follows:

Corporate support charges from Integrated BioPharma decreased to approximately \$314,600 in the fiscal year ended June 30, 2008 from approximately \$430,300 from the fiscal year ended June 30, 2007, a decrease of approximately \$115,700 or 27% as a result of Integrated BioPharma transferring direct payroll costs of approximately \$24,000 directly to us in the fiscal year ended June 30, 2008. The remaining decrease of approximately \$92,000 was the result of our Parent changing the percentage of the overhead allocation to be charged to us from 20% of allocable overhead expenses to 5% and reallocating the officers and administrative salary allocation on a lower percentage basis effective beginning January 2008. These allocations were changed mid year mostly as a result of the addition of our own president, which reduced the decrease in the allocation percentage of certain officers of Integrated BioPharma. Had the allocable percentage remained at 20%, our corporate overhead charges would have been \$110,400 higher. Corporate support charges ceased as of the August 18, 2008, the distribution date of the spin-off from our Parent.



Corporate support charges consisted of the following:

The salary allocation is an allocation of the Integrated BioPharma's salaries and related employee costs for persons in the executive management team that devote a portion of their time to InB:Biotechnologies business and an allocation of the accounting and support staff of Integrated BioPharma whom also devote a portion of their time to our record keeping and administrative matters. The overhead allocation is an allocation of Integrated BioPharma's allocable overhead accounts including office expenses, telephone, professional fees, consulting fees, finance charges and travel and entertainment expenses and are allocated to each of Integrated BioPharma's subsidiaries' based on the estimated percentage of time devoted to each company, including Integrated BioPharma, and actual expenses of Integrated BioPharma on a trailing six month period.

Salaries and employee benefits increased to \$350,800 in the fiscal year ended June 30, 2008 from \$148,700 in the fiscal year ended June 30, 2007, an increase of approximately \$202,100. The increase is primarily attributable to the hiring of our President in October 2007 and other employees between October 2007 and June 2008, increasing our salary costs by approximately \$172,300 and our employee benefit expense by approximately \$29,800 in the fiscal year ended June 30, 2008 compared to no such expense in the comparable period a year ago.

Consulting and other professional fees decreased by approximately \$71,400 or 19.7% in the fiscal year ended June 30, 2008 to approximately \$291,300 compared to approximately \$362,700 in the fiscal year ended June 30, 2007. Consulting and other professional fees consist of legal, outside accounting services, director's fees, scientific advisory board ("SAB") expenses (both travel and consulting fees) and consulting fees paid to outside consultants and our own Chief Scientific Officer. The decrease from the fiscal year ended June 30, 2007 to June 30, 2008 was the result of decreased legal fees of \$81,000 and decreased consulting fees of \$31,200, offset in part by increased SAB costs of \$36,800. Our SAB costs increased by about 119%, as there was one meeting held in the fiscal year ended June 30, 2007 and two meetings were held in the fiscal year ended June 30, 2008.

In December 2006, the Company made an investment in a private biotech company that was in its initial stages of filing to become a public company. In the three month period ended December 31, 2007, the Company, based in part on information from public filings filed in February 2008 by this biotech company, which stated that if the company was unsuccessful in its efforts to raise additional capital, it only had enough cash on hand to cover operating expenses through May 2008 and if it were successful in obtaining additional funding, such financings would have a dilutive effect to current stockholders. Furthermore, this biotech company is not a public company, the financial statements included in the public filing stated that there was substantial doubt about the company's ability to continue as a going concern and there is no established market for the investment we hold, we therefore recorded a valuation reserve equal to our entire investment of \$253,500, in this biotech company.

Depreciation and amortization expense decreased to approximately \$245,300 in the fiscal year ended June 30, 2008 from approximately \$322,100 in the fiscal year ended June 30, 2007, or approximately \$76,800. The decrease is primarily due to an increase in the expected life of our intellectual property acquired from FhCMB from 15 years to 20 years resulting from an amendment of the FhCMB technology agreement at the end of our June 30, 2007 fiscal year end. The decrease of approximately \$106,300 in our intellectual property amortization expense was offset in part, by an increase of \$29,100 in our amortization expense of patents.

In the fiscal year ended June 30, 2008, lab expense increased by \$79,700 to \$116,800 from \$37,100 in the comparable period a year ago, \$41,600 of the increase relates to salaries of employees charged to lab expense. In the fiscal year ended June 30, 2008, an employee's salary of approximately \$38,000 was charged directly to lab expense





as he exclusively works in the lab overseeing the production of the raw material under the Mannatech supply agreement. This employee was transferred from another wholly-owned subsidiary of Integrated BioPharma in January 2007 and was no longer charged through the corporate support allocation. In the six month period ended December 31, 2006, his salary was included in the corporate salary allocation from Integrated BioPharma and in the six month periods ended June 30, 2007 and December 31, 2007, approximately \$37,100 of salary expense was charged to lab expense in both periods. The increase in lab salaries of approximately \$41,600 was a result of hiring additional employees who work on lab projects other than the Mannatech supply agreement in the fiscal year ended June 30, 2008. The remaining change of approximately \$38,100 relates to increased supplies used by the new employees in their project work.

Travel and entertainment expenses increased by \$68,200 to \$95,600 in the fiscal year ended June 30, 2008, from \$27,500 in the fiscal year ended June 30, 2007. This increase was the result of increased travel incurred in connection with our recruiting efforts for our newly hired president who began in October 2007, and additional travel incurred in the 2008 period in connection with our private placement efforts to raise additional capital. Additionally, our president who resides in California, and our Chief Scientific Officer, who resides in London, made several trips to our offices in Delaware and attended various meetings in New York and Florida in the fiscal year ended June 30, 2008 compared to the same period in 2007 resulting in increased travel and lodging costs of \$52,600 and additional meal and entertainment costs of \$15,600.

Other expense increased to approximately \$93,700 in the fiscal year ended June 30, 2008 from approximately \$80,500 in the fiscal year ended June 30, 2007, approximately \$13,200 or 16.4%. As a percentage of total selling and administrative expenses, other expenses were 5.2% and 5.6% in the fiscal years ended June 30, 2008 and 2007, respectively, a decrease as a percentage of the total selling and administrative expenses.

Pursuant to SFAS No. 123(R), adopted as of July 1, 2005, we recognized approximately \$56,000 in compensation expense for employee stock options in the fiscal year ended June 30, 2008 and \$33,700 in the fiscal year ended June 30, 2007. This expense is a direct allocation from our former Parent for our employees and directors who received compensation in the form of stock options providing for the purchase of our Parent's stock upon vesting of their awards.

**Income tax (benefit).** In the fiscal year ended June 30, 2008, the Company had net income tax expense of approximately \$4,000 compared to \$1,000 in the fiscal year ended June 30, 2007. Our ability to recognize an income tax benefit is dependent on the consolidated federal taxable income (loss) of Integrated BioPharma's controlled group for federal income tax purposes. In the fiscal year ended June 30, 2008 and 2007, the controlled group of Integrated BioPharma had a taxable loss and therefore did not utilize any of the losses generated by us and as a stand-alone taxable entity, we would have to reserve 100% of our resulting deferred tax asset generated from the net operating loss as it is more likely than not that, in the near term, that we will not generate sufficient taxable income to offset our Fiscal 2008 and 2007 taxable losses. Our deferred tax asset 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 we 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 following table sets forth, for the periods indicated, the Company's net cash flows used in operating, investing and financing activities:





At June 30, 2008, we had negative working capital of \$1.8 million, an increase from our negative working capital of \$1.2 million, as of June 30, 2007. Our cash position was dependent on our former Parent advancing funds to our operating account on an as needed basis and hence our cash balance as of June 30, 2008 and 2007 was approximately \$19,000 and \$18,800, respectively.

In the fiscal year ended June 30, 2008, we used \$1.1 million of cash from our operating activities compared to \$849,400 of cash in operations in the fiscal year ended June 30, 2007, an increase of approximately \$300,000. The increase of approximately \$300,000 in cash used in operating activities is composed of the increases in; our operating loss of \$6,600 (excluding non-cash activities) and increases in the use of cash of \$33,400 in other assets and decreases in the amount of cash provided in operations from our accounts payable and accrued expenses of \$133,900 and \$307,800, respectively, offset by an increase in cash provided from our accounts receivable of \$181,700.

The decrease in our accounts receivable balance is a result of our increased collections efforts as a result of having a dedicated staff person focused on periodically reviewing our accounts receivable aging with timely follow up with our customers. The increases in account payable and accrued expenses of an aggregate amount of \$157,100 is primarily attributable an increase accrued and unpaid research and development costs of \$100,000 to \$550,000 in 2008 from \$450,000 in 2007.

The decrease in cash used from investing activities of approximately \$775,300 in our fiscal year ended June 30, 2008 from our fiscal year ended June 30, 2007 is partially due to the purchase of other non-current investment assets of \$253,500 in 2007 and no similar purchases in 2008. Additionally, due to a decrease in cash advances from our Parent, we did not make payments of \$750,000 owed to FhCMB during the fiscal year ended June 30, 2008 until subsequent to year end in August 2008, upon the completion of our \$5.0 million private placement of capital.

The decrease in cash provided from financing activities of approximately \$489,500 from fiscal year ended June 30, 2007 to 2008, is a result of a net decrease in advances from our Parent. The following table sets forth the Company's future commitments as of June 30, 2008 (Purchase Obligations represents our expected payments to FhCMB under our amended technology transfer and research agreements):



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 August 2008, we closed on our \$5.0 million private placement (net proceeds of \$4.6 million), which funds were released from an escrow account subsequent to the spin-off. This additional capital is expected to cover our anticipated costs through the first quarter of calendar year 2010. 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 and cease operations.

#### ***Capital Expenditures***

The Company's capital expenditures, other than intellectual property, during the fiscal year ended June 30, 2008 and 2007 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 46, 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 to financial statements at page 40.

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

None.

**Item 9A. Controls and Procedures**

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

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. The Company has not completed its Sarbanes Oxley section 404 evaluation and documentation process, or related assessment, and as a newly public company, is not required to do so until at least its fiscal year ending June 30, 2009. The Company may identify deficiencies that may require remediation in the process of its evaluation and testing.

There have been no changes in our internal controls over financial reporting during the year ended June 30, 2008, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**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, 2008.

#### **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, 2008.

#### **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, 2008.

#### **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, 2008.

#### **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, 2008.





**PART IV****Item 15. Exhibits and Financial Statement Schedules**

## (a) Exhibits and Index

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

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

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- (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*

IBIOPHARMA, INC.  
FINANCIAL STATEMENTS  
AS OF JUNE 30, 2008 AND 2007 AND

FOR THE FISCAL YEARS ENDED JUNE 30, 2008 AND 2007

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**Report of Independent Registered Public Accounting Firm**

We have audited the accompanying balance sheets of iBioPharma, Inc, (formerly, INB: Biotechnologies, Inc., a wholly owned subsidiary of Integrated BioPharma, Inc.) as of June 30, 2008 and 2007 and the related statements of operations, stockholder's 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 iBioPharma, Inc, (formerly, INB: Biotechnologies, Inc., a wholly owned subsidiary of Integrated BioPharma, Inc.) as of June 30, 2008 and 2007, and the results of its operations and its cash flows for each of the years then ended in conformity with U.S. generally accepted accounting principles.

**/s/ Amper, Politziner, & Mattia LLP**

September 26, 2008  
Edison, New Jersey























**iBioPharma, Inc.**  
**(Formerly, InB:Biotechnologies, Inc.)**  
**(A Wholly Owned Subsidiary of Integrated BioPharma, Inc.)**  
**NOTES TO FINANCIAL STATEMENTS**  
**AS OF JUNE 30, 2008 AND 2007 FOR THE**  
**FISCAL YEARS ENDED JUNE 30, 2008 and 2007**

***Note 1. Basis of Presentation and Business***

iBioPharma, Inc., a Delaware Corporation, (formerly InB:Biotechnologies, Inc., a New Jersey corporation) (the “Company”) and a wholly owned subsidiary of Integrated BioPharma, Inc. (the “Parent” or “Integrated BioPharma”), is engaged primarily in the biotechnology business, which is focused on the discovery, development and commercialization of proprietary products from plants. The Company is developing its patented plant-based expression technologies for the production of vaccines, antibodies and other therapeutic proteins. The Company is also using plants as sources of novel, high quality nutritional supplements. The Company’s patented process for the hydroponic growth of edible plants causes them to accumulate high levels of important nutritional minerals. The Company’s customers are located primarily in the United States. The Company was previously known as Nucycle Therapy, Inc. and was incorporated on April 15, 1993 as Phytotech, Inc.

On November 9, 2007, the Board of Directors of our former Parent, approved a plan to distribute its equity interests in the Company to its stockholders. On July 25, 2008 our Parent announced the spin-off of the Company in the form of a dividend. The record date of the dividend was August 12, 2008 with a distribution date of August 18, 2008. Stockholders of our Parent received one share of the Company’s common stock for each share of common stock they owned of our Parent as of the record date. See Note 11- Subsequent Events.

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 periods presented.

***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:

- sales returns and allowances;
- allowance for doubtful accounts;
- valuation and recoverability of long-lived and intangible assets and goodwill, including the values assigned to acquired intangible assets;

- income taxes and valuation allowance on deferred income taxes, and;
- accruals for, and the probability of, the outcome of current litigation, 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 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. Among the factors the Company takes into account in determining the proper time at which to recognize revenue are when title of



**iBioPharma, Inc.**  
**(Formerly, InB:Biotechnologies, Inc.)**  
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**NOTES TO FINANCIAL STATEMENTS**  
**AS OF JUNE 30, 2008 AND 2007 FOR THE**  
**FISCAL YEARS ENDED JUNE 30, 2008 and 2007**

the goods transfers and when the risk of loss transfers. The Company's sales policy is to require customers to provide purchase orders establishing selling prices and shipping terms. The Company evaluates the credit risk of each customer and establishes an allowance of doubtful accounts for any credit risk. Sales returns and allowances are estimated upon shipment.

**Research and Development Costs.** Research and development costs are expensed as incurred. The Company incurred approximately \$550,000 and \$673,000 in the fiscal years ended June 30, 2008 and 2007, respectively.

**Stock-Based Compensation.** As of June 30, 2008, the Company had no stock-based compensation plans. Prior to the spin-off, non-cash compensation earned by employees and directors of the Company were the result of stock options and restricted stock unit awards issued under the Parent's stock based compensation plan.

**Income Taxes.** The Company had elected to file its federal income tax return as part of the consolidated federal tax return of Integrated BioPharma, its then parent company, and accordingly has not filed separate tax returns with the Internal Revenue Service since it has been a wholly owned subsidiary of Integrated BioPharma. For state and local income taxes the Company has and continues to file tax returns separate from its Parent. The Parent and the Company account for the Company's federal tax liabilities on the "separate company basis" method in accordance with FASB Statement No. 109, "Accounting for Income Taxes". Under this method, the Company records tax expense and related deferred tax benefits in a manner comparable to that which it would record if it were not affiliated with Integrated BioPharma.

The Company will file separate federal tax returns beginning in its fiscal year ending June 30, 2009, which will be for the period from August 18, 2008 to June 30, 2009, subsequent filings will be for the Company's entire fiscal year periods ending June 30.

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

**Earnings 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 antidilution limitations.

For the fiscal years ended June 30, 2008 and 2007, 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



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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 and cash equivalents, 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.

**Accounts Receivable and Allowance for Doubtful Accounts.** In the normal course of business, the Company extends credit to customers. Accounts receivable, less allowance for doubtful accounts, reflect the net realizable value of receivables, and approximate fair value. The Company believes there is no concentration of credit risk with any single customer whose failure or nonperformance would materially affect the Company's results other than as discussed in Note 7(c) – Significant Risks and Uncertainties – Major Customers. On a regular basis, the Company evaluates its accounts receivables and establishes an allowance for doubtful accounts based on a combination of specific customer circumstances, credit conditions, and historical write-off and collections. The allowance for doubtful accounts as of June 30, 2008 and June 30, 2007 was \$2,250. Accounts receivable are charged off against the allowance after management determines the potential for recovery is remote.

**Fixed Assets.** Fixed assets are recorded at cost and consist primarily of computer software and are amortized and depreciated over estimated useful lives of 3-5 years.

**Intangible Assets.** Intangible assets with finite lives are amortized over their estimated useful 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. The carrying value of intangible assets with finite lives is evaluated whenever events or circumstances indicate that the carrying value may not be recoverable. 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.

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.

**Recent Accounting Pronouncements.** In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities”, an amendment of FASB SFAS No. 133. SFAS No. 161 requires disclosure of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008, with early adoption permitted. We do not expect SFAS No. 161 to have a material impact on our consolidated financial position, results of operations and cash flows.



In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in financial statements,” an amendment of ARB No. 51. The standard changes the accounting for noncontrolling (minority) interests in financial statements including the requirements to classify noncontrolling interests as a component of consolidated stockholders’ equity, and the elimination of “minority interest” accounting in results of operations with earnings attributable to noncontrolling interests reported as a part of consolidated earnings. Additionally, SFAS No. 160 revises the accounting for both increases and decreases in a parent’s controlling ownership interest. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. We are currently evaluating the impact of the pending adoption of SFAS No. 160 on our financial statements.



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In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB SFAS No. 115,” which allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for certain financial assets and liabilities on an instrument-by-instrument basis. Subsequent measurements for the financial assets and liabilities an entity elects to record at fair value will be recognized in earnings. SFAS No. 159 also establishes additional disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, with early adoption permitted provided that the entity also adopts SFAS No. 157. We do not expect SFAS No. 159 to have a material impact on our consolidated financial position, results of operations and cash flows.

In September 2006, the FASB issue SFAS No. 157, “Fair Value Measurement” (“SFAS No. 157”). SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 17, 2007. In February 2008, the FASB issued FASB Staff Position No. 157-1, “Application of FASB SFAS No. 157 to FASB SFAS No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13 and FASB Staff Position No. SFAS 157-2, Effective Date of SFAS No. 157.” Collectively, the Staff Positions defer the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, for nonfinancial assets and nonfinancial liabilities except for items that are recognized or disclosed at fair value on a recurring basis at least annually, and amend the scope of SFAS No. 157. We are currently evaluating the impact of the pending adoption of SFAS No. 157 on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “Business Combinations.” The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition related restructuring liabilities, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer’s income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited.

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.” FSP SFAS No. 142-3 is effective for fiscal years beginning after December 15, 2008 and early adoption is prohibited. We are currently evaluating the impact of the pending adoption of FSP SFAS No. 142-3 on our financial statements.

In June 2007, the FASB ratified EITF No. 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities: (EITF No. 07-3). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 will not have a material impact on our financial statements.





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***Note 3. Intangible Assets and Other Payables***

The carrying amount of intangible assets as of June 30, 2008 and 2007 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, 2008 and 2007, the Company made payments of \$100,000 and \$600,000, respectively, under an intellectual property acquisition agreement, as amended, with FhCMB entered into in January 2004. As of June 30, 2008 and 2007, the Company has a remaining commitment of \$1,050,000 that will be paid in the fiscal year ending June 30, 2009 and is included in other payables at June 30, 2008 and 2007. Amortization expense recorded on intangible assets for the fiscal years ended June 30, 2008, 2007 and 2006 was approximately \$245,000 and \$289,000, respectively. Amortization expense is recorded on the straight-line method over periods ranging from 10 years to 20 years and is included in selling and administrative expenses.







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The estimated annual amortization expense for intangible assets for the five succeeding fiscal years is as follows as of June 30, 2008:

***Note 4. Due to Parent***

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

The corporate overhead allocation due our Parent are allocated based on the estimated time that the 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 are based on actual costs incurred by our Parent.



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***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, 2008 and 2007 follow:

Federal net operating losses of approximately \$1.5 million were used by Integrated BioPharma and are not available to the Company. Its Parent allocates 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 the control group.

Federal and state net operating losses of approximately \$4.3 million and \$5.8 million are available to the Company and will expire beginning in 2008 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 would be able use these net operating losses to offset future taxable income before the net operating losses expire and the Company 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:



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***Note 6. Profit-Sharing Plan***

The Company is currently included 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 are determined by matching a percentage of employee contributions. The total expense for the fiscal years ended June 30, 2008 and 2007 was approximately \$5,000 and \$6,000, respectively.

***Note 7. Significant Risks and Uncertainties***

***(a) Concentrations of Credit Risk-Cash.*** The Company maintains balances at a financial institution. Deposit accounts at the institution are insured by the Federal Deposit Insurance Corporation for deposits up to \$100,000. As of June 30, 2008, the Company had no uninsured cash balances.

***(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, 2008 and 2007 was \$2,250. The Company's bad debt expense for the fiscal years ended June 30, 2008 and 2007 were none and \$2,250, respectively.

***(c) Major Customers.*** For the fiscal year ended June 30, 2008 approximately 50.6% and 41.5% of revenues were derived from two customers. For the fiscal year ended June 30, 2007 approximately 44.7%, 27.4% and 26.8% of revenues were derived from three customers. The loss of any of these customers would have an adverse affect on the Company's operations. Accounts receivable from these customers represented 53% of the accounts receivable balance as of June 30, 2008.

***(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 turns 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, 2008 and 2007, the Company was invoiced by IHT \$484,500 and \$422,800, 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 its business and assets against insurable risks, to the extent that it deems appropriate, based upon an analysis of the relative risks and costs. The Company believes that the risk of loss from non-insurable events would not have a material adverse effect on the Company's operations as a whole.

***Note 8. Commitments and Contingencies***

**(a) Leases.** The Company leases office space on a month-to-month basis. The lease was effective October 1, 2006 and provides for a minimum monthly rental 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, 2008 and 2007.

**(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.



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("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 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 a maximum purchase price of \$3.6 million.

As of June 30, 2008 and 2007, the Company has made payments of approximately \$2.6 million and \$2.5 million, respectively for the purchase commitment of \$3.6 million, of which \$1.05 million is accrued and is to be paid in fiscal year 2009.

Under the Company's R&D Agreements, if FhCMB achieves each of the targeted Milestones, as defined in the agreements, the Company will incur research and development costs of \$1.2 million in addition to the \$10.0 million under the amended IP Agreement over the course of the next five years.

***Note 9. Equity Transactions***

In connection with the Company entering into a Separation and Distribution Agreement (the "Distribution") with its Parent in November 2007, the Company will restate its stockholder's deficiency to reflect the Distribution transaction, whereby, the Parent has 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 completion of the Distribution was subject to various customary closing conditions, including the declaration by the U.S. Securities and Exchange Commission of the effectiveness of the registration under the Securities Exchange



Act of 1934 of the Company's common stock. The Distribution was completed on August 18, 2008. The Distribution should qualify as a tax-free reorganization under Section 355 of the Internal Revenue Code of 1986, as amended. The Agreement prohibits the Company from issuing any 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. See Note 10. Subsequent Events.



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***Note 10. Subsequent Events***

As disclosed in Note 9, in November 2007, the Company entered into a Separation and Distribution Agreement (the “Distribution”) with its Parent, whereby, the 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 completion of the Distribution was subject to various customary closing conditions, including the declaration by the U.S. Securities and Exchange Commission of the effectiveness of the registration under the Securities Exchange Act of 1934 of the Company’s common stock. The Distribution was completed on August 18, 2008 and each shareholder of our Parent received one share of the Company for each share the shareholder owned as of August 12, 2008, the Record Date. The Distribution should qualify 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.

In August 2008, the Company entered into a Transitional Services Agreement (the “TS Agreement”) with Integrated BioPharma. The transitional services agreement permits us to continue to use certain corporate services previously provided to us by Integrated BioPharma as a subsidiary corporation in exchange for a management charge. The scope of these services is limited to legal, strategic financial planning and SEC reporting, and tax services by certain Integrated BioPharma corporate employees. In exchange for these services, the Company expects to pay approximately \$50,000 for certain financial and tax services over an estimated period of six months; the TS Agreement provides for a per annum fee of \$100,000.

Also as disclosed in Note 9, on August 19, 2008, our Parent entered into a Conversion Agreement, whereby the Parent caused approximately \$5.2 million of the intercompany debt to be contributed to additional paid in capital and used \$2.7 million of the intercompany debt to purchase approximately 1.3 million shares of the Company, representing 6% of the then outstanding shares of the Company. Subsequent to the Company’s private placement as discussed below, Integrated BioPharma owns 5.4% of the Company.

Additionally, on August 19, 2008, the Company closed on its \$5.0 million capital raise (net proceeds of \$4.6 million) 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 approximately 2.3 million 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.





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The following table sets for the Company's capitalization on an actual basis as of June 30, 2008, and as adjusted to give effect to the above transactions as though they had been completed on June 30, 2008:



**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.

**iBioPharma, Inc.**

Date: September 29, 2008

By: /s/ Robert B. Kay  
Robert B. Kay  
Chief Executive Officer

Date: September 29, 2008

By: /s/ Dina L. Masi  
Dina L. Masi  
Interim Chief Financial Officer