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

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2010

OR

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

For the transition period from _____ to _____

Commission File Number 000-53125

iBio, Inc.

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

Delaware	**26-2797813**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
9 Innovation Way, Suite 100, Newark, DE	**19711**
(Address of principal executive offices)	*(Zip Code)*

(302) 355-0650
(Registrant s telephone number, including Area Code)

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

Title of Each Class
Common Stock, $0.001 par value per share

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

Yes o 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 o No x

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

Yes x No o

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

Yes o No o

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

Yes o No x

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

Large accelerated Filer	o
Accelerated Filer	o
Non-accelerated Filer	o
Smaller reporting company	x

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

Yes o No x

The aggregate market value of the voting stock held by non-affiliates of the Registrant based on the trading price of the Registrant s Common Stock on December 31, 2009 was $15,888,279.

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

Class	*Outstanding at October 13, 2010*
Common Stock, $0.001 par value	28,272,655 Shares

DOCUMENTS INCORPORATED BY REFERENCE

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

IBIO, INC.
(Formerly iBioPharma, Inc.)

FORM 10-K ANNUAL REPORT

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K may constitute forward-looking statements as defined in Section 27A of the Securities Act of 1933 (the Securities Act), Section 21E of the Securities Exchange Act of 1934 (the Exchange Act), the Private Securities Litigation Reform Act of 1995 (the PSLRA) or in releases made by the Securities and Exchange Commission (SEC), all as may be amended from time to time. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of iBio, Inc. (the Company) or industry results, to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors including, among others, changes in general economic and business conditions; loss of market share through competition; introduction of competing products by other companies; the timing of regulatory approval and the introduction of new products by the Company; changes in industry capacity; pressure on prices from competition or from purchasers of the Company s products; regulatory obstacles to the introduction of new technologies or products that are important to the Company; availability of qualified personnel; the loss of any significant customers or suppliers; and other factors both referenced and not referenced in this Report. Statements that are not historical fact are forward-looking statements. Forward looking-statements can be identified, by among other things, the use of forward-looking language, such as the words plan , believe , expect , anticipate , intend , estimate , proj will , would , could , should , seeks , or scheduled to , or other similar words, or the negative of these terms or other variations of these t comparable language, or by discussion of strategy or intentions. These cautionary statements are being made pursuant to the Securities Act, the Exchange Act and the PSLRA with the intention of obtaining the benefits of the safe harbor provisions of such laws. The Company cautions investors that any forward-looking statements made by the Company are not guarantees or indicative of future performance. Important assumptions and other important factors that could cause actual results to differ materially from those forward-looking statements with respect to the Company include, but are not limited to, the risks and uncertainties affecting their businesses described in Item 1A of this Annual Report on Form 10-K and in other securities filings by the Company.

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

PART I

Item 1. Business

Overview

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our Business Structure

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

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

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

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

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

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

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

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

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

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

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

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

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

Our Product Candidates

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

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

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

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

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

Pandemic Avian Influenza Vaccine. Through FhCMB and their funding from the Gates Foundation, we are developing vaccine candidates targeting highly pathogenic avian influenza (H5N1) viruses based upon the iBioLaunch platform. These candidates have demonstrated immunogenicity and have been successfully tested in mice and ferrets for protective efficacy. Like our candidate vaccines for seasonal influenza, our candidate vaccines for avian influenza are subunit vaccines. Thus, we do not need to culture the intact avian influenza virus in order to produce our candidate vaccines. The Gates Foundation has committed significant funding to FhCMB for preclinical development and a Phase 1 human clinical trial of this pandemic influenza vaccine candidate using our technology. Our longer term goal is to develop a combined vaccine effective for preventing both seasonal and pandemic influenza infections.

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

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

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

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

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

Target Markets

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

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

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

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

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

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

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

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

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

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

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

Research and Development

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

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

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

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

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

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

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

NA = not applicable UT = untested

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

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

Intellectual Property

We exclusively control intellectual property developed at FhCMB for human health applications of plant-based production and protein expression systems. We also exclusively control the veterinary field for plant-made influenza vaccines. Our success will depend in part on our ability to obtain and maintain patent protection for our technologies and to preserve our trade secrets. Our policy is to seek to protect our proprietary rights, by among other methods, filing patent applications in the U.S. and foreign jurisdictions to cover certain aspects of our technology.

We currently hold four U.S. patents and one international patent. Additionally, we have twelve U.S. and seventy-one international patent applications pending. The latter includes numerous foreign countries including Australia, Brazil Canada, China, Hong Kong, India, Japan, New Zealand, and several countries in Europe. We continue to prepare patent applications relating to our expanding technology in the U.S. and abroad.

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

Issued Technology Filing (U.S.)

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

Sales and Marketing

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

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

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

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

Competition

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

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

Smaller or early stage companies may also prove to be significant competitors, particularly through arrangements with large and established companies, and this may reduce the value of our platform technology for the purposes of establishing license agreements. For example,

Novavax is developing vaccines for influenza, based on the use of cultured insect cells. Its candidate products are more advanced in development than ours are and have already demonstrated positive results in human clinical trials. Similarly, Medicago has conducted a Phase 1 clinical study of an influenza vaccine produced in green plants. Other companies, such as Vical, are attempting to develop vaccines based on the use of nucleic acids rather than proteins. If these efforts are successful in clinical trials, nucleic acid based vaccine products may compete effectively against our products and may potentially prevent us from being able to obtain commercial agreements or partnerships to enter the market.

In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

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

There are currently approved therapies for the diseases and conditions addressed by our vaccine and therapeutic protein candidates that are undergoing clinical trials and for the diseases and conditions that are subjects of our preclinical development program. There are also a number of companies working to develop new drugs and other therapies for diseases of commercial interest to us that are undergoing various stages of testing including clinical trials. The key competitive factors affecting the success of our platform for commercial product candidates are likely to be efficacy, safety profile, price, and convenience.

Government Regulation and Product Approval

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacture and marketing of pharmaceutical drugs and vaccines. All of the vaccine, therapeutic or diagnostic products developed from our platform technology will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical drugs and vaccines are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the Food & Drug Administration (FDA) and regulatory authorities in other countries. In the U.S., various federal, and, in some cases, state statutes and regulations, also govern or impact the manufacturing, safety, labeling, storage, record-keeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, if and when obtained for any of our product candidates, may be limited in scope, which may significantly limit the indicated uses for which our product candidates may be marketed. Further, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown

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

Before testing any compounds with potential therapeutic value in human subjects in the U.S., we must satisfy stringent government requirements for preclinical studies. Preclinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. *In vitro* refers to tests conducted with cells in culture and *in vivo* refers to tests conducted in animals. Preclinical testing results obtained from studies in several animal species, as well as data from *in vitro* studies, are submitted to the FDA as part of an Investigational New Drug application (IND) and are reviewed by the FDA prior to the commencement of human clinical trials. These preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers. In the case of candidate vaccine products, animal immunogenicity and immune protection tests must establish a sound scientific basis to believe that the product candidate may be beneficial when administered to humans.

In order to test a new biologic product or vaccine in humans in the U.S., an IND must be filed with the FDA. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concern or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. For additional information on the most recent FDA regulations and guidance on vaccine and therapeutic product testing and approval, visit its website at http://www.fda.gov.

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

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

The product testing and clinical trial requirements that must be met before a product candidate can be marketed are substantial, time-consuming, and require investments of millions of dollars per product candidate. We must test our vaccine candidates for safety in Phase 1 clinical trials. Vaccine candidates for use in preventing disease will be administered to healthy people, and,

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

Product Liability

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

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

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

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

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

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

Our insurance may not provide adequate protection against potential liabilities.

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

Employees

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

Available Information

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

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

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

Item 1A. Risk Factors

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

Risks Related to Our Business

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

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

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

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

Our licensees will not be able to commercialize product candidates based on our platform technology if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans.

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

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

Initial clinical results may not be supported by further or more extensive clinical trials. For example, a licensee may obtain data that suggest a desirable immune response from a vaccine candidate in a small human study, but when tests are conducted on larger numbers of people, the same extent of immune response may not occur. If the immune response generated by a vaccine is too low or occurs in too few treated individuals, then the vaccine will have no commercial value.

Enrollment in our licensee s clinical trials may be slower than projected, resulting in significant delays. The cost of conducting a clinical trial increases as the time required to enroll adequate numbers of human subjects to obtain meaningful results increases. Enrollment in a clinical trial can be a slower-than-anticipated process because of competition from other clinical trials, because the study is not of interest to qualified subjects, or because the stringency of requirements for enrollment limits the number of people who are eligible to participate in the clinical trial.

Our licensee might have to suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks. Animal tests do not always adequately predict potential safety risks to human subjects. The risk of any candidate product is unknown until it is tested in human subjects, and if subjects experience adverse events during the clinical trial, the trial may have to be suspended and modified or terminated entirely.

Regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements.

Any regulatory approval ultimately obtained may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable.

The effects of our licensee s product candidates may not be the desired effects or may include undesirable side effects.

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

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

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

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

- Our ability to advance product candidates based on our technology into development with licensees;
- The success of our anticipated commercial agreements with licensees;
- Our ability to establish and maintain additional development agreements or other alternative arrangements;
- The timing of, and the costs involved in, obtaining regulatory approvals;
- The cost of manufacturing activities;
- The cost of commercialization activities, including marketing, sales and distribution;
- The costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including, if necessary, litigation costs and the results of such litigation; and
- Potential acquisition or in-licensing of other products or technologies.

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

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

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

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

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

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

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

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do.

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

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

Finally, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

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

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

We expect to rely upon our future business arrangements for support in advancing certain of our drug candidates and intend to rely on addit