iBio, Inc.
Form S-3/A
March 14, 2011

As filed with the Securities and Exchange Commission on March 14, 2011

Registration No. 333-171315

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

AMENDMENT NO. 3 ON FORM S-3
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

IBIO, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**2834**	**26-2797813**
(State of Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

9 Innovation Way, Suite 100, Newark, Delaware 19711
(Address of Principal Executive Offices, including Zip Code)

Robert B. Kay
Chief Executive Officer
9 Innovation Way, Suite 100
Newark, Delaware 19711
(302) 355-0650
(Name, Address and Telephone Number of Agent for Service)

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with copies to:

Andrew Abramowitz, Esq.
Andrew Abramowitz, PLLC
565 Fifth Avenue
9th Floor
New York, New York 10017
(212) 972-8883 (fax)

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following
box: o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities pursuant to Rule 413(b) under the Securities Act, check the following box: o

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

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

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY STATEMENT

This Amendment No. 3 on Form S-3 is a Pre-Effective Amendment to the Registration Statement on Form S-1, filed by the registrant on December 21, 2010, prior to the registrant becoming eligible to use Form S-3 for a secondary offering of securities.

This registration statement contains a prospectus to be used in connection with the potential resale by certain selling stockholders of:

1. 4,000,000 shares of common stock sold to investors in a private offering in October and November, 2010;
2. 4,000,000 shares of common stock issuable upon exercise of warrants issued to investors in the above offering;
3. 824,324 shares of common stock issuable upon exercise of warrants issued to service providers in 2010;
4. 2,848,696 shares of common stock issuable upon exercise of warrants issued to investors in a private offering in August 2008 (as adjusted to reflect anti-dilution adjustments made following our 2009 and 2010 offerings); and
5. 3,000,000 shares of common stock underlying stock options held by private investors to purchase shares currently held by E. Gerald Kay and Carl DeSantis, two of our significant stockholders.

Pursuant to Rule 429 of the Securities Act of 1933, the prospectus which is a part of this registration statement is a combined prospectus and includes all of the information currently required in a prospectus relating to the securities described in item 4 above, which were included in Registration Statement No. 333-162424, as well as the securities described in item 5 above, which were included in Registration Statement No. 333-167361, which was withdrawn before effectiveness. This registration statement also constitutes a Post-Effective Amendment to Registration Statement No. 333-162424.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 14, 2011

PROSPECTUS

14,673,020 Shares

COMMON STOCK

This prospectus relates to the offer for sale of 14,673,020 shares of common stock, par value $0.001 per share, by the existing holders of the securities named in this prospectus, referred to as selling stockholders throughout this prospectus. Of these shares, 7,673,020 are issuable upon the exercise of outstanding warrants. We will receive none of the proceeds from the sale, except upon exercise of the warrants.

The selling stockholders may sell the common stock from time to time on any stock exchange or automated interdealer quotation system on which the securities are listed, in the over-the-counter market, in privately negotiated transactions or otherwise, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at prices otherwise negotiated.

Our common stock is listed on the NYSE Amex market under the symbol IBIO. On March 9, 2011, the last reported sales price of our common stock on the NYSE Amex market was $2.97 per share.

The selling stockholders and intermediaries through whom the common stock is sold may be deemed underwriters within the meaning of the Securities Act of 1933 or the Securities Act with respect to the securities offered hereby, and any profits realized or commissions received may be deemed underwriting compensation. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act.

Investing in our common stock involves a high degree of risk. We urge you to read carefully the section entitled Risk Factors beginning on page 2 of this prospectus, the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended June 30, 2010, and all other information included or incorporated by reference into this prospectus in its entirety before purchasing any of our common stock offered under this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2011.

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You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the selling stockholders has authorized anyone to provide you with additional or different information. If anyone provides you with additional, different, or inconsistent information, you should not rely on it. Neither we nor the selling stockholders are making an offer to sell securities in any jurisdiction in which the offer or sale is not permitted. You should assume that the information in this prospectus is accurate only as of the date on the front cover of this prospectus, and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, in each case, regardless of the time of delivery of this prospectus. Our business, financial condition, results of operations, and prospects may have changed since such date. In this prospectus, the Company, iBio , we, us and our refer to iBio, Inc.

SUMMARY PROSPECTUS

This summary highlights information contained elsewhere in this prospectus or incorporated by reference herein. This summary is not complete and may not contain all of the information that you should consider before deciding whether or not you should purchase our common stock offered hereunder. You should read the entire prospectus carefully, including the section entitled Risk Factors beginning on page 2 of this prospectus and the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended June 30, 2010, and all other information included or incorporated herein by reference in this prospectus before you decide whether to purchase our common stock.

Our Company

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

In order to attract appropriate licensees and increase the value of our share of such intended contractual arrangements, we engaged the Center for Molecular Biology of Fraunhofer USA, Inc. (FhCMB) in 2003 to perform research and development activities to apply the platform 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 its research and development activities, 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. Two of these vaccine candidates began a Phase 1 clinical trial during late calendar year 2010.

Our Corporate Information

We are a Delaware corporation. Our principal executive/administrative offices are located at 9 Innovation Way, Suite 100, Newark, Delaware 19711, and our telephone number is (302) 355-0650. Our website address is http://www.ibioinc.com. Information on or accessed through our website is not incorporated into this prospectus and is not a part of this prospectus. Our common stock is listed on the NYSE Amex market under the symbol IBIO.

The Offering

Common stock offered by selling stockholders	14,673,020 shares, consisting of 7,000,000 outstanding shares owned by selling stockholders and 7,673,020 shares issuable upon the exercise of certain warrants held by the selling stockholders.
Common stock outstanding before the offering	32,292,254 shares.
Common stock outstanding after the offering	39,965,274 shares. (1)
Proceeds to us	We will not receive any of the proceeds from the sale of the shares of common stock because they are being offered by the selling stockholders. We are not offering any shares for sale under this prospectus. However, we will receive the proceeds from any exercise of the warrants, which would be used for general corporate and working capital purposes.
Risk factors	See Risk Factors beginning on page 2 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the common stock.

1 Assumes the exercise of warrants to purchase 7,673,020 shares held by selling stockholders.

RISK FACTORS

Our past experience may not be indicative of future performance, and as noted elsewhere in this prospectus and documents incorporated by reference into this prospectus, we have included forward-looking statements about our business, plans and prospects that are subject to change. In addition to the other risks or uncertainties contained in this prospectus and documents incorporated by reference into 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 Relating 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, which includes our $8.0 million private placement of common stock that closed in November 2010, as described herein, will be sufficient to meet our projected operating requirements through the balance of calendar 2011. 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 and cease operations.

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

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

revenues from sales of our potential products, business arrangements and other sources. Some of these fluctuations may be significant.

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

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

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

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

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

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

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

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

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

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

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

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

- Future agreements may be for fixed terms and subject to termination under various circumstances, including, in some cases, on short notice without cause.
- Our future licensees may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the agreement with us.
- Our future licensees may underfund or not commit sufficient resources to the testing, marketing, distribution or other development of our products.
- Our future licensees may not properly maintain or defend our intellectual property rights, or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential liability.
- Our future licensees may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries. The ability of our product candidates and products to reach their potential could be limited if our licensees or customers decrease or fail to increase spending relating to such products.

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

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

If we fail to establish commercial licenses for our platform technology or fail to enter into arrangements with partners with respect to the sales and marketing of any of our future potential product candidates, we would need to develop a sales and marketing organization with supporting distribution capability in order to directly market our technology and/or related products. Significant additional expenditures would be required for us to develop such an in-house sales and marketing organization.

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

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

additional alternative arrangements. The terms of any additional arrangements that we establish may not be favorable to us. Moreover, these arrangements may not be successful.

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

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

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

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

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

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

There can be no assurance that:

- Patent applications owned by or licensed to us will result in issued patents;
- Patent protection will be secured for any particular technology;
- Any patents that have been or may be issued to us will be valid or enforceable;
- Any patents will provide meaningful protection to us;
- Others will not be able to design around the patents; or
- Our patents will provide a competitive advantage or have commercial application.

The failure to obtain and maintain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing of any product. Please see 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 Business Intellectual Property for more information on our current patents and patent applications. We could incur substantial costs in proceedings, including interference proceedings before the United States Patent and Trademark Office and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our or our licensors inventions and products, as well as about the enforceability, validity or scope of protection afforded by the patents. Any adverse decisions about the patentability of our product candidates could cause us to either lose rights to develop and commercialize our product candidates or to license such rights at substantial

cost to us. In addition, even if we were successful in such proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

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

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

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

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

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

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

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

Clinical trial and product liability insurance is volatile and may become increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or

product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- Liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- An increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- Withdrawal of clinical trial volunteers or patients;
- Damage to our reputation and the reputation of our products, resulting in lower sales of any future commercialized product which we may have;
- Regulatory investigations that could require costly recalls or product modifications;
- Litigation costs; or
- The diversion of management s attention from managing our business.

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

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

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

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

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

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

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

Our independent registered public accounting firm, J.H. Cohn LLP (JHC), communicated to our audit committee on February 10, 2010 that a material weakness existed in our internal control over financial reporting. This weakness was comprised of financial accounting and disclosure deficiencies and financial reporting deficiencies for non-routine, complex transactions. This weakness resulted in us not implementing the guidance in ASC 815-40, Derivative and Hedging Contracts in an Entity s Own Equity in a timely manner, which required the restatement of our financial statements as of and for the quarter ended September 30, 2009, and additions and corrections to disclosures in our Form 10-Q. If we fail in the remediation

of future material weaknesses, if any, it could diminish our future ability to meet our financial reporting obligations in an accurate and timely manner.

Risks Relating to our Common Stock

We have a history of losses and may not be able to generate sufficient revenue and/or obtain adequate amounts of financing in the future to support operations and/or achieve profitability.

We have incurred losses since inception. To date, our expenses have primarily consisted of research and development and general and administrative expenses related to the development and commercialization of our proprietary technology. Our financial statements have been prepared assuming that we will continue as a going concern.

We intend to continue to finance the development and commercialization of our proprietary technology through revenue generated from licensing fees and services provided to our clients and collaborators and/or raise additional funds.

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

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

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

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

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

Diluting the voting or other rights of the proposed acquirer or insurgent stockholder group,

Putting a substantial voting block in institutional or other hands that might undertake to support the incumbent board of directors, or

Effecting an acquisition that might complicate or preclude the takeover.

Our certificate of incorporation also allows our board of directors to fix the number of directors in the by-laws. Cumulative voting in the election of directors is specifically denied in our certificate of incorporation. The effect of these provisions may be to delay or prevent a tender offer or takeover attempt that a stockholder may determine to be in his, her or its best interest, including attempts that might result in a premium over the market price for the shares held by the stockholders.

We also are subject to Section 203 of the Delaware General Corporation Law. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless the transaction in which the person became an interested

stockholder is approved in a manner presented in Section 203 of the Delaware General Corporation Law. Generally, a business combination is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of a corporation s voting stock. This statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

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

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

A significant number of our shares will be eligible for sale and their sale or potential sale may depress the market price of our common stock.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. This prospectus covers 14,673,020 shares of our common stock, including shares of our common stock underlying currently outstanding warrants, representing (assuming exercise of such warrants) approximately 36.7% of our outstanding shares of our common stock. As additional shares of our common stock become available for resale in the public market pursuant to this offering, and otherwise, the supply of our common stock will increase, which could decrease its price. Some or all of the shares of common stock may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares of common stock. Subject to certain restrictions, a person who has held restricted shares for a period of six months may sell common stock into the market.

FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference forward-looking statements that involve risks and uncertainties. These forward-looking statements are not historical facts but rather are plans and predictions based on current expectations, estimates and projections about our industry, our beliefs and assumptions. We use words such as anticipate, expect, intend, plan, believe, seek, estimate and variations of t words and similar expressions to identify forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and other factors, some of which are beyond our control, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. These risks and uncertainties include those described in the section above entitled Risk Factors. You should not place undue reliance on these forward-looking statements, which reflect our view only as of the date of this prospectus.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the common stock by any selling stockholders. All proceeds from the sale of the common stock will be paid directly to the selling stockholders. We may receive proceeds from the exercise of the warrants. The holders of the warrants are not obligated to exercise the warrants and we cannot assure that the holders of the warrants will choose to exercise all or any of the warrants.

We intend to use the estimated net proceeds received upon exercise of the warrants, if any, for working capital and general corporate purposes.

SHARES REGISTERED FOR RESALE

This prospectus covers the following securities registered for resale:

4,000,000 shares of our common stock, plus an additional 4,000,000 shares of common stock issuable upon exercise of warrants, sold to investors in a private offering in October and November 2010;

824,324 shares of common stock issuable upon exercise of warrants issued to service providers in 2010;

2,848,696 shares of common stock issuable upon exercise of warrants issued to investors in a private offering in August 2008 (as adjusted to reflect anti-dilution adjustments made following our 2009 and 2010 offerings); and

3,000,000 shares of common stock underlying stock options held by private investors to purchase shares currently held by E. Gerald Kay and Carl DeSantis, two of our significant stockholders. See Selling Stockholders.

SELLING STOCKHOLDERS

The following table sets forth the name of each of the selling stockholders, the number of shares beneficially owned by each of the selling stockholders as of January 14, 2011, the number of shares that may be offered under this prospectus and the number of shares of our common stock owned by each of the selling stockholders after the offering is completed. The information concerning the selling stockholders may change from time to time, which changed information will be set forth in supplements to this prospectus if and when necessary. Because the selling stockholders may offer all or some of the common stock held, we can only give an estimate as to the amount of common stock that will be held by the selling stockholders upon the termination of this offering.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting and investment power with respect to securities. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in this table has sole voting and investment power with respect to the shares shown as beneficially owned by him or her.

As of January 14, 2011, 2010, 32,292,254 shares of our common stock were outstanding. In computing the number of shares beneficially owned by a person and the percentage of ownership of that person, shares of common stock issuable upon the exercise of warrants and options that are currently exercisable or exercisable within 60 days of January 14, 2011, are deemed to be outstanding and beneficially owned by the person holding the options, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Under this prospectus, the selling stockholders and any of their respective transferees, assignees, donees, distributees, pledgees or other successors in interest to the common stock covered by this prospectus may offer and sell from time to time an aggregate of up to 14,673,020 shares of common stock.

On May 21, 2010, two of our significant stockholders, E. Gerald Kay and Carl DeSantis, entered into agreements with two private investors, Kobus Investments, LLC and BioMed Investments, LLC, affiliates of Noble International Investments, Inc., described below, pursuant to which such investors obtained an option to purchase up to 3,000,000 shares of our common stock from such stockholders, with the shares purchased upon each exercise to be sold in equal amounts by Mr. Kay and Mr. DeSantis (or an affiliate of Mr. DeSantis). Such shares may be purchased at certain times during the 270-day period commencing with the effective date of the registration statement of which this prospectus is part. For each of the two agreements, the exercise price at which these LLCs may purchase such shares ranges from $0.50 per share for the first 250,000 shares purchased by each investor to $1.75 per share for the last 250,000 shares subject to the option, with an average exercise price of $1.125 per share. The right to purchase the lowest-priced shares ($0.50 and $0.75) subject to the option expires 180 days after the effective date of the registration statement, followed by the mid-priced shares ($1.00 and $1.25), for which the right expires 210 days after the effective date of the registration statement, followed by the highest-priced shares ($1.50 and $1.75), for which the right expires 270 days after the effective date of the registration statement.

In a private placement conducted in October and November of 2010, we sold 4,000,000 shares of common stock at a purchase price of $2.00 per share, and issued to the investors warrants to purchase an additional 4,000,000 shares of common stock with an exercise price of $2.20, for gross proceeds of $8,000,000. We are registering the shares of common stock sold to investors, along with the shares of common stock issuable upon exercise of the warrants, for the 2010 private placement investors identified in the selling stockholder table pursuant to a Registration Rights Agreement with the investors to (i) file a registration statement with respect to the resale of shares of the common stock sold to the investors with the Securities and Exchange Commission within 30 days after the final closing date of November 22, 2010; (ii) use our reasonable best efforts to have the registration statement declared effective by the SEC as soon as possible after the initial filing; and (iii) use our reasonable best efforts to keep the registration statement effective until the earlier of the time when all shares registered thereunder have been sold or the shares covered by the registration statement may be sold without volume restrictions pursuant to Rule 144.

Certain selling stockholders including Nico Pronk, Wayne Horne and and Shawn Titcomb are affiliates of Noble International Investments, Inc., a FINRA registered broker-dealer that served as the Placement Agent in the 2010 private placement. We paid Noble International approximately $530,000 and issued it five-year cashless exercise warrants to purchase 249,324 shares of common stock at exercise prices ranging from $2.16 to $2.93 per share, based on our closing stock price on the date of each closing of the private placement, pursuant to a Placement Agent Agreement, dated October 27, 2010, between us and Noble

International. The warrants are transferable to Noble International s employees and affiliates. Noble International received one time piggyback registration rights with respect to the common stock underlying the warrants.

Noble International also entered into a two-year Advisory Agreement with us effective July 13, 2010. Under the Advisory Agreement, we pay Noble International a $15,000 per month financial advisory fee. Also we issued it five-year warrants to purchase 500,000 shares of our common stock, exercisable at $1.10 per share, subject to vesting at a rate of 20,000 shares per month. The warrants are transferable to Noble International s employees and affiliates and carry one-time piggyback registration rights for the common stock underlying such warrants.

There are currently no agreements, arrangements or understandings with respect to the sale of any of the resale shares held by the selling stockholders, except for that certain Registration Rights Agreement, between the Company and certain of the selling stockholders enumerated below, the Placement Agent Agreement, the Advisory Agreement and the Option Agreements.

Name	Shares of Common Stock Beneficially Owned Before the Offering	Shares of Common Stock Registered in this Offering	Shares of Common Stock Owned After Offering	Percentage of Outstanding Common Stock Beneficially Owned After the Offering
Ethel and Philip Adelman Charitable Foundation, Inc. (1)	500,000	500,000	0	*
Ayer Capital Partners Kestrel Fund, LP (2)	45,634	45,634	0	*
Ayer Capital Partners Master Fund, L.P. (3)	1,329,312	1,329,312	0	*
Arron Banks	200,000	200,000	0	*
Jeffrey Benison	147,000	50,000	97,000	*
Vernon Ross Biggers	25,000	25,000	0	*
BioMed Investments, LLC (4)	1,500,000	1,500,000	0	*
Alberta Bove	25,000	25,000	0	*
Joseph D. Bove Jr.	25,000	25,000	0	*
Brio Capital L.P. (5)	100,000	100,000	0	*
CD Financial, LLC (6)	5,551,419	500,000	5,051,419	15.6%
Michael Cerisano	40,000	20,000	20,000	*
Michael and Patricia Cerisano (as Tenants in Common)	30,000	20,000	10,000	*
Patricia Cerisano	44,000	28,000	16,000	*
Cranshire Capital, LP (7)	95,000	95,000	0	*
T. Wayne Davis	143,360	74,066	69,294	*
Tine W. Davis Foundation (8)	100,000	100,000	0	*
Robert W. Doherty	380,000	80,000	300,000	*
Epworth-Ayer Capital (9)	125,054	125,054	0	*
John Brent Evans	25,000	25,000	0	*
Christopher E. Fay	300,000	300,000	0	*
Martin J. Ferkin	50,000	50,000	0	*
Tony D. Fiest	25,000	25,000	0	*