DOR BIOPHARMA INC
Form 424B3
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PROSPECTUS

DOR BioPharma, Inc.

9,962,500 Shares of Common Stock

This prospectus relates to the sale of up to 9,962,500 shares of our common stock by Fusion Capital Fund II, LLC. Fusion Capital is sometimes referred to in this prospectus as the selling stockholder. The prices at which Fusion Capital may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Fusion Capital.

Our common stock is quoted on the American Stock Exchange under the symbol "DOR." On February 6, 2006, the last reported sale price for our common stock as reported on the American Stock Exchange was $0.44 per share. The shares of common stock offered pursuant to this prospectus have been approved for trading on the American Stock Exchange.

Investing in the common stock involves certain risks. See "Risk Factors" beginning on page 5 for a discussion of these risks.

The selling stockholder is an "underwriter" within the meaning of the Securities Act of 1933, as amended.

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 March 6, 2006

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You should rely only on the information contained or incorporated by reference in this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with different information.

We have not authorized the selling stockholder to make an offer of these shares of common stock in any jurisdiction where the offer is not permitted.

You should not assume that the information in this prospectus or prospectus supplement is accurate as of any date other than the date on the front of this prospectus.

FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements as defined in the Private Securities Reform Act of 1995. These forward-looking statements are often identified by words such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “contin and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to make certain that our cash expenditures do not exceed projected levels;
- our ability to obtain future financing or funds when needed;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- our ability to successfully obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;
- our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;
- our ability to patent, register and protect our technology from challenge and our products from competition;
- maintenance or expansion of our license agreements with our current licensors;
- our ability to maintain our listing on the American Stock Exchange;
- maintenance of a successful business strategy;
- the FDA not considering orBec® approvable based upon existing studies because orBec® did not achieve statistical significance in its primary endpoint in the pivotal Phase III clinical study (i.e. a p-value of less than or equal to 0.05);
- orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, if required, or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- we are dependent on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;
- orBec® may not gain market acceptance;
- others may develop technologies or products superior to our products.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

PROSPECTUS SUMMARY

The Company

We are a biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of intestinal Graft-versus-Host Disease, "iGVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of iGVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs when resources permit; and (j) acquire or in-license new clinical-stage compounds for development.

Our principal executive offices are located at Lincoln Building, 1691 Michigan Ave., Miami, Florida 33139 and our telephone number is 305-534-3383.

orBec®

Our goal is to file an NDA with the FDA for orBec® for the treatment of iGVHD in the first quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of iGVHD to be between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also evaluating an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. The outcome of the study was recently published in the online edition of the Proceedings of the National Academy of Sciences. In January of 2005 we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the second milestone of

fermentation and downstream process development under their development and manufacturing agreement.

Botulinum Programs

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date, demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™ a high yield expression system based on *Pseudomonas fluorescens.* Up to this point we have successfully demonstrated successful high expression of soluble material from all three Hc50 vaccine candidates.

Botulinum Toxic Therapeutics

In 2005, we entered into an agreement with Blue Dolphin, LLC, a firm specializing in rational drug development, to apply computer-aided design to the discovery of small molecule drugs to counter Botulinum toxin exposure. Under the agreement, Blue Dolphin is exploring novel drug-like inhibitors of Botulinum toxin by targeting a new site on the toxin's structure. Candidate molecules will be modeled for structural and chemical fit to the target site on the toxin using computer aided discovery techniques. The best fitting molecules will be experimentally tested for their effectiveness in treating Botulinum toxin exposure. By focusing on the structure of the Botulinum toxin, as opposed to derivatives of previously known inhibitors, this "virtual screening" will allow DOR to target new parts of the toxin with new candidate inhibitors. To date, we have identified several lead inhibitors. Planned studies will focus on initial profiling of hits and validation testing for activity against botulinum toxin exposure, in addition to investigating the mechanism of action of confirmed quality hits.

We will apply for research grants and contracts from the U.S. government to continue development of these programs. The goal of our biodefense programs is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

Recent Development—Expiration of Material Letter of Intent with Gastrotech Pharma

On October 28, 2005, we entered into a binding letter of intent to acquire Gastrotech Pharma A/S (“Gastrotech”), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. On January 26, 2006, we advised Gastrotech that we were not renewing the letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1 million break-up fee in the event a party notifies the other of its intention not to proceed with the transaction. Our position is that we do not owe Gastrotech such break-up fee.

The Offering

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions, including that the registration statement of which this prospectus is a part of is declared effective by the SEC, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over approximately a 15-month period, subject to earlier termination at our discretion. In our discretion, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12.

Fusion Capital is offering for sale up to 9,962,500 shares of our common stock. In the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,117,439, i.e., greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

As of February 6, 2006, there were 50,872,504 shares outstanding, excluding the 9,962,500 shares offered by Fusion Capital pursuant to this prospectus which have not yet been issued by us. If all of the shares offered by this prospectus were issued and outstanding as of the date hereof, the number of shares offered by this prospectus would represent approximately 16.4% of the total common stock outstanding as of February 6, 2006.

We are also registering for sale any additional shares of common stock which may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

On February 13, 2006, the registration statement of which this prospectus is a part was declared effective by the SEC. On March 6, 2006, the conditions for commencement of sales of our shares to Fusion Capital specified in the common stock purchase agreement were satisfied.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and related notes.

Risks Related To Our Industry

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts and we may be unable to continue our operations.

We are a company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2005, we had approximately $1.8 million in cash available. We expect that we will need additional sources of funding to meet our cash requirements for the next twelve months. In addition, through a National Institute of Health grant, a portion of our personnel and overhead expenditures will be supported. All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through September 30, 2005, we had expended approximately $12.2 million developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $8.0 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our leading product candidate, or another one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.12. Since we initially registered 9,000,000 shares for sale by Fusion Capital pursuant to this prospectus (excluding the 900,000 commitment fee shares and 62,500 expense reimbursement shares that we have registered), the selling price of our common stock to Fusion Capital will have to average at least $0.67 per share for us to receive the maximum proceeds of $6.0 million without registering additional shares of common stock. Assuming a purchase price of $0.44 per share (the closing sale price of the common stock on February 6, 2006), proceeds to us would only be $3,960,000 unless we choose to register more than 9,962,500 shares, which we have the right to do. Subject to approval by our board of directors, we have the right under the common stock purchase agreement to issue more than 9,962,500 shares to Fusion Capital. In the event we elect to issue more than 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the U.S. Securities & Exchange Commission.

In addition, in the event that we decide to issue more than 10,117,439 (19.99% of our outstanding shares of common stock as of the date of our agreement), we would first be required to seek stockholder approval in order to be in compliance with the American Stock Exchange rules. We currently do not intend to seek stockholder approval to effect sales to Fusion Capital in excess of 10,117,439 shares.

If we are unsuccessful in developing our products, our ability to generate revenues will be significantly impaired.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and preclinical development and will require significant further funding, research, development, preclinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our other product candidates:

·we will not be able to maintain our current research and development schedules;

·we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;

·we will encounter problems in clinical trials; or

·the technology or product will be found to be ineffective or unsafe.

If any of the risks set forth above occurs, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

·it is uneconomical or the market for the product does not develop or diminishes;

·we are not able to enter into arrangements or collaborations to manufacture and/or market the product;

·the product is not eligible for third-party reimbursement from government or private insurers;

·others hold proprietary rights that preclude us from commercializing the product;

·others have brought to market similar or superior products; or

·the product has undesirable or unintended side effects that prevent or limit its commercial use.

Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

Our business is subject to very stringent United States, federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational

Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may be unable to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed. The pivotal clinical trial of our product candidate orBec® began in 2001. In December of 2004, we announced top line results for our pivotal Phase III trial of orBec® in iGVHD, in which orBec® demonstrated a highly statistically significant reduction in mortality during the prospectively defined Day 200 post-transplant period and positive trends on its primary endpoint. While orBec® did not achieve statistical significance in its primary endpoint of time to treatment failure at Day 50 (p-value 0.1177), orBec® did achieve a statistically significant reduction in mortality compared to placebo. We plan to file a new drug application with the FDA. Additional clinical trials may be necessary prior to either submission of a marketing application or approval by the FDA of a marketing application.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the United States and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine is safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the two animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the two animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

We will be dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant non-government commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent almost entirely upon government spending decisions. The

funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

Our products, if approved, may not be commercially viable due to health care changes and third party reimbursement limitations.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from, the University of Texas Southwestern Medical Center, The University of Texas Medical Branch at Galveston, Thomas Jefferson University, Southern Research Institute, the University of Alabama Research Foundation, and George B. McDonald M.D. for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. Development of an effective sales force would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may not be able to compete successfully with our competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel disease. We face intense competition in the area of biodefense from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the United States Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the United States are maintained in secrecy until patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The Patent and Trademark Office may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We have only ten employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Michael Sember, Chief Executive Officer, was hired in December 2004; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was on the Board for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In the fourth quarter of 2004, Alexander P. Haig was appointed Chairman of the Board replacing his father, General (Ret.) Alexander M. Haig, Jr., who resigned from our Board and joined our BioDefense Strategic Advisory Board. Because of this inexperience in operating our business, there continues to be significant uncertainty as to how our management team will perform. We will not be successful if this management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Risks Related to the Offering

Our stock price is highly volatile.

The market price of our common stock, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so in the future due to a wide variety of factors, including:

- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our quarterly operating results and performance;
- announcements by us or others of results of pre-clinical testing and clinical trials;
- developments or disputes concerning patents or other proprietary rights;
- acquisitions;
- litigation and government proceedings;

· adverse legislation;

· changes in government regulations;

· economic and other external factors; and

· general market conditions

Our per share stock price has fluctuated between January 1, 2001 through February 6, 2006 between a high of $2.10 per share to a low of $0.11 per share. As of February 6, 2006, the closing sale price of our common stock was $0.44. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock may not remain listed on the American Stock Exchange

Because we continue to incur losses from operations in fiscal 2005, the stockholders' equity standard applicable to us of the American Stock Exchange's (AMEX) continued listing requirements is $6 million. As of September 30, 2005, we had stockholders' equity of $3,519,342.

In June 30, 2003, our net equity of $2.3 million did not satisfy the $4 million minimum stockholders' equity requirement that was applicable to calendar quarters ending during 2003, and we received notification from the AMEX that we were no longer in compliance with their minimum listing requirements. This requirement was increased to $6 million minimum stockholders' equity for fiscal years ending 2003 and beyond. On August 4, 2003 we submitted a compliance plan, and the AMEX accepted our plan and allowed us 18 months to regain compliance in accordance with the terms of our plan. Our deadline to meet the plan was December 26, 2004, to avoid delisting from the AMEX. Although we did not meet the plan submitted, AMEX provided us with the opportunity to submit a new plan of compliance with the listing standard, which we submitted on December 30, 2004. On January 24, 2005 AMEX accepted the compliance plan and provided us until July 12, 2005 to comply with the continued listing standard of section 1003 (a) (iii) of the AMEX company guide. This compliance date was then extended by AMEX until October 15, 2005. On such date, we did not have $6 million in stockholders' equity. Therefore on October 26, 2005, the Company received notice from the AMEX staff indicating that the Company no longer complies with AMEX's continued listing standards because the Company had shareholders' equity of less than $6.0 million and losses from continuing operations and/or net losses in its five most recent fiscal years, as set forth in Section 1003(a)(iii) of the Company Guide, and that the AMEX intends to proceed with removal of the Company's common stock from listing and registration on AMEX. The Company appealed this determination and requested a hearing before a committee of the AMEX which was held on December 2, 2005. In addition, on November 22, 2005, the Company received notice from the AMEX staff indicating that the Company also no longer complies with AMEX's continued listing standards because the Company had shareholders' equity of less than $4.0 million and losses from continuing operations and/or net losses in three of its four most recent fiscal years, as set forth in Section 1003(a)(iii) of the Company Guide. AMEX also considered this deficiency at the hearing on December 2, 2005. On December 8, 2005, we received notice from AMEX that we had been granted an extension until March 31, 2006 to regain compliance with AMEX's rules. If we have not done so by that date, AMEX will delist us with no further opportunity to appeal. We cannot assure you that we will regain compliance by March 31, 2006 nor can we assure you that we will continue to satisfy other requirements necessary to remain listed on the AMEX or that the AMEX will not take additional actions to delist our common stock.

If our stock were to be delisted from the AMEX, we may not be able to list our common stock on another national exchange or market. If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Upon any such delisting, our common stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than $5.00 per share, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided

that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, if our common stock were to become subject to the penny stock rules, it is likely that the price of our common stock would decline and that our stockholders would find it more difficult to sell their shares.

Stockholders may suffer substantial dilution.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 22.2 million shares of our common stock at a current weighted average exercise price of approximately $0.93;

- anti-dilution rights associated with a portion of the above warrants which can permit purchase of additional shares and/or lower exercise prices under certain circumstances; and

- options to purchase approximately 10.3 million shares of our common stock at a current weighted average exercise price of approximately $0.59.

To the extent that anti-dilution rights are triggered, or warrants or options are exercised, our stockholders will experience substantial dilution and our stock price may decrease.

Shareholders are also subject to the risk of substantial dilution to their interests as a result of our issuance of shares under the common stock purchase agreement. See "—Holders of our common stock are subject to the risk of additional and substantial dilution to their interests as a result of the issuances of common stock to Fusion Capital." We are also involved in negotiations that could result in the issuance of a significant number of shares of our equity securities. This transaction could result in substantial dilution to our existing stockholders.

The purchase by Fusion Capital may not be available when we need it, thus limiting our ability to continue our product development and commercialization.

We cannot begin sales of our common stock to Fusion Capital until the effectiveness of the registration statement of which this prospectus is a part and the common stock purchase agreement may be terminated in the event of a default under the agreement. In addition, Fusion Capital does not have the right or the obligation to purchase any shares of our common stock if the purchase price is less than $0.12 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. See "Fusion Transaction."

Holders of our common stock are subject to the risk of additional and substantial dilution to their interests as a result of the issuances of common stock to Fusion Capital.

Shareholders are subject to the risk of substantial dilution to their interests as a result of our issuance of shares under the common stock purchase agreement. The sale by the selling stockholder of our common stock as contemplated by this prospectus will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by the selling stockholder as contemplated by this prospectus could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock. In addition, in the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. If such registration were declared effective by the SEC, Fusion Capital could also sell any shares registered on such a subsequent registration statement and this in turn would result in additional dilution to our other stockholders. If we elect to issue more than the 9,962,500 shares offered hereby and the average price at which we sell $6.0 million of our stock is $0.44 (the closing sale price of our common stock on February 6, 2006) we would issue 13.7 million shares. We do not have the right to sell shares to Fusion Capital at a price below $0.12 per share and accordingly we could not issue more than 50,000,000 shares under the agreement.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares in this offering are freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by this prospectus will be sold over a period of in excess of 15 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Contemplated transactions could cause our stock to be held by a small group of stockholders and result in a change in control.

We are presently involved in negotiations that could result in the issuance of an additional significant number of shares of senior equity securities to a small number of investors that, if successful, could result in a change in control in a series of one or more transactions. Such potential new investors would be able to effectively or actually control all matters requiring approval by stockholders, including the election of directors, the approval of amendments to our charter and approval of significant corporate transactions. The interests of these stockholders may differ from the interests of other stockholders since they may be issued with rights and preferences that are senior to those of our current stockholders, and their concentration of ownership could have the effect of causing our current stockholders to lose the control premium currently associated with their shares by denying stockholders the ability to vote upon subsequent change in control transactions of the company. Depending upon the structure of such one or more series of new issuance of stock, stockholders may not be afforded an adequate opportunity to vote on the terms of such series of transactions. Such potential concentration of ownership or change in control could also have the effect of delaying or preventing a change in control of our business or otherwise discouraging a potential acquirer from attempting to take control of us, even if the transactions would be beneficial to our other stockholders.

If the market price of our common stock declines, we may be unable to utilize the Fusion Capital agreement without requesting our shareholders to approve the issuance of more than 19.99% of our common stock or registering additional shares, both of which would impose additional costs and time delays.

If the market price of our common stock declines, the number of shares of common stock issuable in connection with the Fusion Capital agreement will increase. Accordingly, we may be required to ask our shareholders to approve issuances over 19.99% of our common stock as required under AMEX rules or we may run out of shares registered under this registration statement to issue to the investor in connection with our use of the Fusion Capital agreement. In such an event, we would be required to ask our shareholders to approve such issuance and/or would be required to file additional registration statements to cover the resale of additional shares, both of which would impose additional

costs and time delays.

Our shares of common stock are thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

Our common stock has from time to time been "thinly-traded", meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Fusion Capital's purchase and sale into the market of $20,000 of our common stock could cause our common stock price to decline due to the additional shares available in the market, particularly in light of the relatively thin trading volume of our common stock. Using the closing price on February 6, 2006, of $0.44 as an example, Fusion Capital would be issued approximately 45,455 shares each trading day if we elected to have them purchase the $20,000 daily purchase amount, whereas our average trading volume for the three months ending on February 6, 2006, is approximately 412,173 per day. The market price of our common stock could decline given our minimal average trading volume compared to the number of shares potentially issuable to Fusion Capital, and the voting power and value of your investment would be subject to continual dilution if Fusion Capital purchases the shares and resells those shares into the market, although there is no obligation for Fusion Capital to sell such shares. Any adverse affect on the market price of our common stock would increase the number of shares issuable to Fusion Capital each trading day which would increase the dilution of your investment. Although we have the right to reduce or suspend Fusion Capital purchases at any time, our financial condition at the time may require us to waive our right to suspend purchases even if there is a decline in the market price.

Contractual 9.9% beneficial ownership limitations prohibit Fusion Capital, together with its affiliates, from beneficially owning more than 9.9% of our outstanding common stock. This 9.9% limitation does not prevent Fusion Capital from purchasing shares of our common stock and then reselling those shares in stages over time so that Fusion Capital and its affiliates do not, at any given time, beneficially own shares in excess of the 9.9% limitation. Consequently, these limitations will not necessarily prevent substantial dilution of the voting power and value of your investment.

BUSINESS

Overview

We are a biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of intestinal Graft-versus-Host Disease, "iGVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of iGVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs when resources permit; and (j) acquire or in-license new clinical-stage compounds for development.

orBec®

Our goal is to file an NDA with the FDA for orBec® for the treatment of iGVHD in the first quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of iGVHD to be at between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also evaluating an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. The outcome of the study was recently published in the online edition of the Proceedings of the National Academy of Sciences. In January of 2005 we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the second milestone of fermentation and downstream process development under their development and manufacturing agreement. RiVax™ is being developed for intramuscular delivery. We are also working on a formulation technology that could permit the vaccine to be delivered nasally, with the objective of providing immunity in the respiratory tract.

Botulinum Programs

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A, B, and E consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™ a high yield expression system based on *Pseudomonas fluorescens*. Up to this point, we have demonstrated high expression of soluble material from all three Hc50 fragments.

Botulinum Toxic Therapeutics

In 2005, we entered into an agreement with Blue Dolphin, LLC, a firm specializing in rational drug development, to apply computer-aided design to the discovery of small molecule drugs to counter Botulinum toxin exposure. Under the agreement, Blue Dolphin is exploring novel drug-like inhibitors of Botulinum toxin by targeting a new site on the toxin's structure. Candidate molecules will be modeled for structural and chemical fit to the target site on the toxin using computer aided discovery techniques. The best fitting molecules will be experimentally tested for their effectiveness in treating Botulinum toxin exposure. By focusing on the structure of the Botulinum toxin, as opposed to derivatives of previously known inhibitors, this "virtual screening" will allow DOR to target new parts of the toxin with new candidate inhibitors. To date, we have identified several lead inhibitors. Planned studies will focus on initial profiling of hits and validation testing for activity against botulinum toxin exposure, in addition to investigating the mechanism of action of confirmed quality hits.

We will apply for research grants and contracts from the U.S. government to continue development of these programs. The goal of our biodefense programs is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

BioDefense Programs

In collaboration with two United States academic research institutions, we are developing vaccine products to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits retain the ability to induce antibodies that completely neutralize the toxins from which they are derived. Through exclusive licenses with these Universities, we have secured important intellectual property rights related to these vaccines.

Ricin Toxin Vaccine

Ricin toxin is a heat stable toxin that is easily isolated and purified from the bean of the castor plant. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control and Prevention (CDC) have classified ricin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

The development of our vaccine against ricin toxin stems from the research (Smallshaw *et al.,* 2002 *Vaccine*) of Dr. Ellen Vitetta at the University of Texas Southwestern (UTSW) Medical Center in Dallas, Texas. This research has shown that a modified subunit of ricin toxin is non-toxic and highly immunogenic in animals, reproducibly inducing protective immunity in mice challenged with ricin toxin. The ricin vaccine is being developed simultaneously along two parallel development tracks: one track leading to a traditional injected vaccine given intramuscularly, while the other track involves the development of an alternate route of delivery, specifically via the intranasal route. The intranasal ricin vaccine is designed to stimulate antibodies at the lung and gastrointestinal epithelial surfaces to neutralize the toxin before cellular damage to the lungs and gastrointestinal tract can occur. In an effort to enhance the efficacy of the nasal vaccine, we are testing the antigen in combination with several delivery systems under a Small Business Innovation Research grant awarded to us in August 2003. This route of administration is a highly desirable alternative to intramuscular administration for two reasons. First, nasal administration enables large groups of individuals to self-administer the vaccine in the event of a mass civilian-based crisis such as the contamination of the water or food supply with ricin toxin. Second, mucosal administration will confer increased protection in the lungs and gastrointestinal tissue which would potentially protect against inhalation or ingestion of ricin toxin.

The vaccine has previously been shown to be effective in generating protective immunity in animals against exposure to lethal doses of ricin toxin (Smallshaw *et al.,* 2002 *Vaccine*). In collaboration with UTSW, we have developed a stable formulation of the vaccine for injection. Based on the preclinical safety and efficacy testing of the vaccine, an Investigational New Drug application (IND) was filed with the FDA through UTSW, and a Phase I trial was initiated in the fourth quarter of 2004. This trial is a dose escalating trial designed to evaluate the safety of the vaccine doses that induce neutralizing antibodies in humans. Concurrently, we are developing processes for manufacturing the vaccine at scale with Cambrex under the auspices of a $6.4 million NIH challenge grant awarded to foster development and manufacturing. Pending evaluation of the safety and immunogenicity results of the first Phase I trial, expected during the second quarter of 2005, we are planning additional clinical trials in humans. In addition, we are planning to conduct pivotal animal trials of the vaccine to elaborate on the FDA “two animal” rule, which permits licensure of vaccines based on the results of safety tests in humans and efficacy results in animals in situations where the evaluation in humans is ethically not permitted. In the case of ricin, it is not ethical to expose humans to ricin post vaccination, so “correlates of immunity” must be established in animal models. Our goal is to make a ricin vaccine available for the United States government’s Strategic National Stockpile. We have an exclusive license agreement with UTSW for its ricin vaccine technology.

Botulinum Toxin Vaccine

Botulinum toxin is the product of the bacteria *Clostridium botulinum*. Botulinum toxin is one of the most poisonous natural substances known to mankind. Botulinum toxin causes acute, symmetric, descending flaccid paralysis due to its action on peripheral cholinergic nerves. Paralysis typically presents 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include respiratory support and passive immunization with antibodies which must be administered before symptoms occur, which leaves little time post-exposure for effective treatment.

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania (Park and Simpson 2003 *Infection and Immunity*). There are seven different serotypes of botulinum toxin and no cross immunogenicity exists between these serotypes. Any vaccine will

therefore require multiple antigens to protect against the different serotypes. The antigen consists of a segment of the heavy chain of botulinum toxin that is non-toxic and immunogenic. After oral or intranasal immunization, the antigen elicits antibodies that protect vaccinated animals against 30,000 times the lethal dose of native toxin. Ability for a subunit protein to induce antibodies after oral or nasal immunization is atypical for protein subunit vaccines and is due to one of the properties that account for the high toxicity of the native toxin: the ability of the heavy chain to bind and be taken up by epithelial cells in the gastrointestinal and respiratory tract. We are currently validating the safety and efficacy data in further animal studies, and extending the results to other serotype, using vaccines made from heavy chain segments from the most prevalent of the serotypes and the ones most likely to be used in biowarfare. Most of the work completed to date involves a single serotype, but we believe that once development of the "prototype" antigen is complete, work on the other serotypes will occur in parallel at an accelerated pace. Our immediate plans are to obtain antigen from a single serotype (through manufacture or collaboration), conduct the necessary preclinical toxicology tests for an IND, and test an oral formulation for safety and immunogenicity in human volunteers. Our goal is to produce a multivalent vaccine and make it available for the U.S. government's Strategic National Stockpile. We have an exclusive license agreement with Thomas Jefferson University for the oral and intranasal use of their botulinum toxin vaccine technology.

Strategy for development of BioDefense products

Since 2001, the United States government has developed an initiative to stockpile countermeasures and vaccines for over 30 biological threats that could be used in bioterrorist attacks or on the battlefield. The Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID) have recognized threats based on several factors: 1) public health impact based on illness and death; 2) ability for an agent to be disseminated, produced, and transmitted from person to person; 3) public perception and fear; and 4) special public health preparedness needs. This prioritization has resulted in classification into three threat categories: A, B, and C, where agents in Category A have the greatest potential for adverse public health impact, and agents in Category B have potential for large scale dissemination, but generally cause less illness and death. Biological agents that are not regarded to present a high public health risk but may emerge as future threats, as the scientific understanding of the agents develops, have been placed in Category C. Very few countermeasures or vaccines currently exist for Category A, B, or C agents. We believe that we have identified and will continue to identify products with relatively low development risk for addressing biological threats in Category A (e.g., botulinum toxin) and B (e.g., ricin toxin). Biodefense products can be developed and sold to the U.S. government before the FDA has licensed them for commercial use. Secondly, the FDA itself has facilitated the approval process, whereby portions of the human clinical development pathway can be truncated. Under the two animal rule, when it is not ethical to perform human efficacy trials, the FDA can rely on safety evidence in humans and evidence from animal studies to provide substantial proof of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the toxicity of the agent and its prevention or cure by the product. This effect has to be demonstrated in more than one animal species expected to react with a response predictive of humans or in one animal species. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies allows selection of an effective dose in humans. Biodefense products are eligible for priority review in cases where the product is a significant advance for a serious or life threatening condition. The government would also purchase countermeasures upon expiration, so there is a recurrent market to replenish the stockpile. Under a $ 5.6 billon appropriation bill over 10 years, the BioShield Act of 2004 authorizes the government to procure new countermeasures. This bill also allows the NIH to use simplified and accelerated peer-review and contracting procedures for research and development and empowers the FDA to approve distribution of unapproved medical products on an emergency basis. Further, there are additional legislation in front of Congress, such as BioShield II, that will address additional issues such as patent extension and liability that may be of benefit to the Company in this business.

BioTherapeutics Division

orBec®

Our therapeutic product orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. orBec® has recently completed a multicenter, placebo-controlled pivotal Phase III clinical trial in iGVHD. iGVHD is a life threatening complication of allogeneic bone marrow transplantation for which no FDA-approved therapies exist, making it an area of unmet medical need. The active ingredient in orBec®, beclomethasone 17, 21-dipropionate ("BDP"), is a mucosally active anti-inflammatory agent, with a potent local effect, that is the active ingredient in a variety of currently marketed products including Beconase Aqua (nasal spray for rhinitis), Becloforte (inhalant for asthma), and Propaderm (a topical cream for eczema and psoriasis). There currently is no FDA-approved oral BDP product in the United States. There are a variety of additional gastrointestinal disorders for which a potent, topically-active oral corticosteroid could be beneficial including Irritable Bowel Syndrome, Ulcerative Colitis and Crohn's Disease. We believe that topical steroids such as orBec® delivered to the affected mucosa would suppress the inflammation associated with these disorders while producing fewer adverse side effects than systemic corticosteroids such as prednisone.

orBec® is manufactured as a two-pill formulation (1 mg BDP per pill) administered four times daily (total of 8 mg) for the indication of acute iGVHD. The two-pill combination is comprised of an immediate-release pill designed to primarily dissolve in the stomach and proximal intestine and an enterically-coated pill designed to dissolve in the more alkaline pH portion of the small intestine.

Phase II Clinical Trial

In the Phase II study, 60 patients with iGVHD were randomized to receive an induction course of conventional prednisone therapy plus either oral beclomethasone dipropionate or placebo. Initial responders continued to take oral beclomethasone or placebo for an additional 20 days, during which time the prednisone therapy was rapidly tapered. The primary endpoint for this study was the clinically relevant determination of whether iGVHD patients at Day 30 were or were not able to consume at least 70% of their daily caloric intake by mouth. The treatment response at study day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the oral beclomethasone and placebo groups respectively, achieving a statistically significant p-value of 0.02. This data was previously published in the journal Gastroenterology (1998).

Pivotal Phase III Clinical Trial

Phase II data demonstrated that the two-pill combination of oral BDP was effective in treating iGVHD, allowing patients to be rapidly tapered off the systemic corticosteroid prednisone, without recurrence of intestinal symptoms (McDonald *et al*., 1998 *Gastroenterology*), and without clinical manifestation of adrenal suppression (Baehr *et al*., 1995 *Transplantation*). Based on this data, we designed a Phase III clinical protocol that was subject to a Special Protocol Assessment (SPA) by the FDA and was similar in design to the previously completed Phase II trial (McDonald *et al.* 1998 *Gastroenterology*). The primary efficacy endpoint of this trial is the time to treatment failure at Study Day 50. Treatment failure was defined as use of prednisone or equivalent IV corticosteroids at doses higher than stated in protocol, or use of any additional other steroid, in response to uncontrolled signs or symptoms of iGVHD. The target enrollment was 130 patients. The pivotal trial was conducted at sixteen bone marrow transplant centers fourteen in the United States and two in France, and the product has been assigned "orphan drug" designation and "fast track" status by the FDA. The trial was a randomized, double-blind, placebo controlled safety, efficacy and pharmacokinetic trial that was to serve as the basis for a New Drug Application to be filed with the FDA.

While orBec® did not achieve statistical significance in its primary endpoint of time to treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in its secondary endpoint of time to treatment failure through Day 80 (p-value 0.0226). The Company believes that the p-value of 0.1177 achieved in the primary endpoint through Day 50 is primarily due to a higher than expected rate of treatment failures during days 0-10 of the study. During such period, patients were receiving high dose prednisone (1-2mg/kg/day) plus either orBec® (8mg/day) or placebo. For purposes of the study, patients that did not begin the rapid taper of high dose prednisone on Day 10 as called for by the regimen were deemed treatment failures for all purposes, including the calculation of statistical

significance of time to treatment failure at Day 50. The Company intends to further analyze the Day 0-10 treatment failure group and the statistical impact of this group on the primary endpoint of time to treatment failure at Day 50 and discuss the results of this analysis with the FDA. Encouragingly, the treatment failure rate at Day 50 approached statistical significance (p-value 0.0515). In addition, the secondary endpoint of time to treatment failure at Day 80, as well the treatment failure rate at Day 80, each achieved statistical significance (p-values 0.0226 and 0.0048, respectively).

Perhaps of greatest clinical relevance, orBec® demonstrated a 70% reduction in mortality, registering only 5 (8%) deaths during the prospectively defined Day 200 post-transplant period versus 16 (26%) deaths for the placebo group (p-value 0.011). Based upon separate analysis conducted by the Company, there is also a statistically significant correlation between treatment failure and mortality.

New Mortality Findings

In response to a specific FDA request and as part of its process to submit a New Drug Application ("NDA"), DOR collected further mortality data from its Phase II and Phase III clinical trials. The new survival analysis of patients enrolled in the earlier Phase II trial suggests that results were similar to those from the pivotal Phase III multi-center study. In the Phase II trial, there were reductions in the risk of mortality of 55% and 43% at transplant day-200 and one-year post-randomization among patients randomized to beclomethasone dipropionate, respectively. The comparable survival data from the 129-patient Phase III pivotal trial were 66% and 51% reductions in the risk of morality at transplant day-200 and one-year post-randomization among patients randomized to orBec®, respectively. In the Phase III pivotal trial, a subgroup analysis revealed that among patients who had received stem cells from unrelated donors, the reduction in the risk of day-200 mortality among patients randomized to orBec® was 94%.

We are currently investigating the possibility of conducting a clinical trial that would test the effectiveness of orBec® for the prevention of iGVHD. If the data from this clinical trial demonstrates positive results, the potential market for orBec® would expand to include all patients in the U.S. who undergo allogeneic bone marrow transplants who are at risk for developing iGVHD.

About Graft-versus-Host Disease

Graft-versus-Host Disease occurs in patients following an allogeneic bone marrow transplant in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes in the donor (graft) marrow. Patients with mild to moderate iGVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of iGVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50 to 70% of the estimated 10,000 annual allogeneic transplant patients in the United States will develop some form of acute iGVHD.

iGVHD is one of the most common causes for the failure of bone marrow transplant procedures. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. orBec® Represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat iGVHD. Currently approved systemic immunosuppressives utilized to control iGVHD substantially inhibit the highly desirable graft-versus-leukemia ("GVL") effect of bone marrow transplants, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

Future Potential Indications of orBec®

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent (6,096,731) claiming the use

of oral BDP as a method for preventing the tissue damage that is associated with both iGVHD following hematopoietic cell transplantation, as well as Host-versus Graft Disease, as occurs following organ allograft transplantation. In addition, we are exploring the possibility of testing orBec® for local inflammation associated with Ulcerative Colitis, Crohn's Disease, Lymphocytic Colitis, Irritable Bowel Syndrome and liver disease, among other indications.

Summary of Our Products in Development

The following tables summarize the products that we are currently developing:

Biodefense Products

Select Agent	Currently Available Countermeasure	DOR Biodefense Product
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricin Vaccine Phase I Clinical Trial Successfully Completed
Ricin Toxin	No vaccine or antidote currently FDA approved	Nasal Ricin Vaccine
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral/Nasal Botulinum Vaccine
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral Botulinum Therapeutic

BioTherapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of Intestinal Graft-versus-Host Disease	Pivotal Phase III Clinical Trial Completed, NDA to be filed
Oraprine™	Oral lesions resulting from Graft-versus-Host Disease	Phase I
LPM™ - Leuprolide	Endometriosis and Prostate Cancer	Pre-Clinical
LPE™ and PLP™ Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

Summary of Other Products in BioTherapeutics Pipeline

The following is a brief description of other products in our pipeline. Due to resource limitations, the Company has recently focused its R&D efforts on orBec®, RiVax® and BT-Vacc™. When financial circumstances change, the Company may re-initiate development of any or all of these products, all of which are currently available for licensing or acquisition. These products consist of two drug delivery systems that are designed to facilitate the oral delivery of hydrophobic and hydrophilic drugs, including peptides, and an oral form of the immunosuppressant azathioprine. We acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001, also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase bioequivalence trial following a trail conducted by Dr. Epstein that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease. The drug delivery systems, LPM™, LPE™, PLP™, including the use of leuprolide in the LPM™ system, were developed internally and we have submitted and pursued patents on these products.

Oraprine™

Oraprine™ is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. Also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase I bioequivalence trial following a trial conducted by Dr. Epstein that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient. Oraprine™ may provide a convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

LPM™ - Leuprolide

LPM™ - Leuprolide is an oral dosage formulation of the peptide drug leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, which utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs

We were developing two lipid-based systems, LPE™ and PLP™, to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE™ system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents. We have filed for patent applications on the use of perillyl alcohol as a solvent, surfactant and absorption enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs.

The Drug Approval Process

General

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FDA and applicable agencies in other countries. Testing, manufacturing, commercialization, advertising, promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation by government authorities in the United States and other countries. All products must go through a series of tests, including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary.

Our products will require, prior to commercialization, regulatory clearance by the FDA and by comparable agencies in other countries. The nature and extent of regulation differs with respect to different products. In order to test, produce and market certain therapeutic products in the United States, mandatory procedures and safety standards, approval processes, manufacturing and marketing practices established by the FDA must be satisfied.

An Investigational New Drug Application (IND) is required before human clinical use in the United States of a new drug compound or biological product can commence. The IND includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase I trials are concerned primarily with the safety of the product. Phase II trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase III trials are expanded multi-center clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship, discover less common side effects and adverse reactions, and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase IV, or post-marketing, studies to be

conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes may be required to be submitted to the FDA or foreign regulatory authority.

In the United States, the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the Federal Food, Drug, and Cosmetic Act involving medical devices.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the two animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and the Company may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the two animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

Marketing Strategies

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We are actively seeking a partner for the development of other potential indications of orBec® as well as for our Oraprine™, LPM™ - Leuprolide, LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs. We are currently evaluating an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

We intend to market our biodefense vaccine products directly to government agencies. We believe that both military and civilian health authorities of the United States and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we currently have. Another source of competing technologies is universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, and we face competition from other companies to acquire rights to those technologies.

Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Avant Immunotherapeutics, Inc., Bioport Corporation, VaxGen, Inc., Chimerix, Inc., Biosante, Inc., ID Biomedical Corporation, Human Genome Sciences, Inc., CpG Immunotherapeutics, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., and others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. VaxGen and Avecia Biotechnology, Inc. have both received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen has also recently received approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of Anthrax vaccine. CpG Immunotherapeutics, Inc. has received a $6 million Department of Defense grant to develop vaccine enhancement technology. ID Biomedical Corporation, has entered into an $8 million contract to develop a plague vaccine. We have not yet been awarded any such contract funding. Additionally, we face competition from other companies which have existing governmental relationships, such as Dynport Vaccine Company, LLC, a prime contractor to the U.S. Department of Defense. Dynport currently has a $300 million contract to develop vaccines for the U.S. Military, including anthrax, and botulinum toxin vaccines.

orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat graft-vs.-host disease by suppressing the immune system through various mechanisms. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat graft-vs.-host disease. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat graft-vs.-host disease. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant related therapeutics.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product Remicade™ for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename

of Entocort®. Entocort is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In Italy, Chiesi Pharmaceuticals markets an oral formulation of beclomethasone dipropionate, the active ingredient of orBec® for ulcerative colitis and may seek marketing approval for their product in countries other than Italy including the United States. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis called Colazal®.

Several companies have also established various colonic drug delivery systems to deliver therapeutic drugs to the colon for treatment of Crohn's disease. These companies include Ivax Corporation, Inkine Pharmaceutical Corporation, and Elan Pharmaceuticals, Inc. Other approaches to treat gastrointestinal disorders include antisense and gene therapy. Isis Pharmaceuticals, Inc. is in the process of developing antisense therapy to treat Crohn's disease.

We are not aware of any marketed products or products in active development to selectively treat iGVHD. We also believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make orBec® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We have "Orphan Drug" designations in the United States and in Europe. Our Orphan Drug designations provide for seven years of post approval marketing exclusivity in the U.S. and 10 years exclusivity in Europe for the use of orBec® in the treatment of iGVHD. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the seven year post-approval exclusivity provided by the Orphan Drug Act of 1983. We are the exclusive licensee of an issued U.S. patent that covers the use of orBec® for the prevention of iGVHD.

Under the Waxman-Hatch Act, a patent which claims a product, use or method of manufacture covering drugs and certain other products may be extended for up to five years to compensate the patent holder for a portion of the time required for development and FDA review of the product. The Waxman-Hatch Act also establishes periods of market exclusivity, which are periods of time ranging from three to five years following approval of a drug during which the FDA may not approve, or in certain cases even accept, applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and efficacy data.

orBec® License Agreement

In October 1998, our subsidiary, Enteron Pharmaceuticals, Inc. (Enteron), entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, M.D., including the right to grant sublicenses, for the

rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDonald receives $40,000 per annum as a consultant to us.

Enteron also executed an exclusive license to patent applications for "Use of Anti-Inflammatories to Treat Irritable Bowel Syndrome" from the University of Texas Medical Branch-Galveston. Under the license agreements, we will be obligated to make performance-based milestone payments, as well as royalty payments on any net sales of orBec®.

Microvax™ Intellectual Property

During 1998, our former joint venture with Élan Pharmaceuticals, Inc., Innovaccines Corporation, acquired from the Southern Research Institute/University of Alabama broadly issued U.S. and international patents relating to the oral administration of vaccines. Microspheres of these dimensions are preferentially absorbed by lymphoid tissues in the gastrointestinal tract and other mucosal lymphoid tissue, resulting in higher efficacy for orally and mucosally applied vaccines. In 2002, we acquired Élan's interest in Innovaccines. We subsequently amended our existing agreement with the Southern Research Institute/University of Alabama for rights to use their patents and technologies for commercialization of microencapsulated vaccines that permit oral delivery of antigenic compounds (vaccines). In April 2003, after the inception of our biodefense program, the license agreement was amended to provide us with the rights to nasal delivery of anthrax and ricin antigens. In keeping with our current focus, the Southern Research Institute/University of Alabama license agreement has again been amended to allow us to keep the nasal rights for the ricin vaccine while returning all other rights. This most recent amendment requires us to pay a yearly license fee in the amount of $60,000 and monthly patent maintenance of $5,000.

Ricin Vaccine Intellectual Property

In January 2003, we executed a worldwide exclusive option to license patent applications with the University of Texas Southwestern Medical Center for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine for initial license fees of $200,000 of our common stock and $100,000 in cash. Subsequently, in October of 2004, we negotiated the remaining oral rights to the ricin vaccine for additional license fees of $150,000 in cash. Our license obligates us to pay $50,000 in annual license fees.

Botulinum Toxin Vaccine Intellectual Property

In 2003, we executed an exclusive license agreement with Thomas Jefferson University for issued U.S. Patent No. 6,051,239 and corresponding international patent applications broadly claiming the oral administration of nontoxic modified botulinum toxins as vaccines. The intellectual property also includes patent applications covering the inhaled and nasal routes of delivery of the vaccine. This license agreement required that we pay a license fee of $160,000, payable in $130,000 of restricted common stock and $30,000 in cash. We also entered into a one-year sponsored research agreement with the execution of the license agreement with Thomas Jefferson University, renewable on an annual basis, under which we are providing $300,000 in annual research support. In addition, we also executed a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine for a period of three years. Under this agreement, Dr. Simpson received options to purchase 100,000 shares of our common stock, vesting over two years. We are also required to pay a $10,000 non-refundable license royalty fee no later than January 1 of each calendar year.

Employees

As of February 6, 2006, we had eight full-time employees, two of whom are Ph.D.s.

Research and Development Spending

We spent approximately $3.4 million and $3.6 million on research and development for the years ended 2005 and 2004, respectively.

DESCRIPTION OF PROPERTY

Our executive offices are located in a leased facility of approximately 2,500 square feet in Miami, Florida. The lease expires on August 31, 2006. We believe that our current leased facilities are sufficient to meet our current and foreseeable needs.

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this Annual Report which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this Prospectus. See "Forward-Looking Statements."

Business Overview and Strategy

We are a biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of intestinal Graft-versus-Host Disease, "iGVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of iGVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs when resources permit; and (j) acquire or in-license new clinical-stage compounds for development.

orBec®

Our goal is to file an NDA with the FDA for orBec® for the treatment of iGVHD in the first quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of iGVHD to be between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also evaluating an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

The scientific development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. The outcome of the study was recently published in the online edition of the Proceedings of the National Academy of Sciences. In January of 2005 we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the second milestone of fermentation and downstream process development under their development and manufacturing agreement. RiVax™ is being developed for intramuscular delivery. We are also working on a formulation technology that could permit the vaccine to be delivered nasally, with the objective of providing immunity in the respiratory tract.

Botulinum Programs

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A and B consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date, demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E; multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals and formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™, a *Pseudomonas*-based technology that accelerates speed to market for vaccines and biotherapeutics by surpassing the quality and yield capabilities of existing microbial systems. In a very short duration, we have demonstrated successful high expression of soluble material from all three Hc50 fragments.

Botulinum Toxic Therapeutics

In 2005, we entered into an agreement with Blue Dolphin, LLC, a firm specializing in rational drug development, to apply computer-aided design to the discovery of small molecule drugs to counter the deadly effects of Botulinum toxin exposure. Under the agreement, Blue Dolphin is exploring novel drug-like inhibitors of Botulinum toxin by targeting a new site on the toxin's structure. Candidate molecules will be modeled for structural and chemical fit to the target site on the toxin using computer aided discovery techniques. The best fitting molecules will be experimentally tested for their effectiveness in treating Botulinum toxin exposure. By focusing on the structure of the Botulinum toxin, as opposed to derivatives of previously known inhibitors, this "virtual screening" will allow DOR to target new parts of the toxin with new candidate inhibitors. To date, we have identified several lead inhibitors. Planned studies will focus on initial profiling of hits and validation testing for activity against botulinum toxin exposure, in addition to investigating the mechanism of action of confirmed quality hits.

We will apply for research grants and contracts from the U.S. government to continue development of these programs. The goal of our biodefense programs is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate these estimates and judgments.

Research and Development

Currently, the most significant estimate or judgment that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". Based on this consideration, we capitalized all outside legal and filing costs incurred in the procurement of patents, as well as amounts paid allowing us to license additional methods of vaccine delivery through the Southern Research Institute patents, shares issued to acquire Élan's interest in the Innovaccine's Joint Venture, and amounts paid to University of Texas Southwestern Medical Center allowing us the ability to license certain patents related to a vaccine protecting against ricin toxin. These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

Revenue Recognition

We recognize revenue from government grants. These revenues are recorded in the period in which they are earned. The consideration we receive is based upon a cost plus Facilities and Administrative (F&A) rate. This F&A rate is a rate that provides funding for overhead expenses. In the second quarter of 2005, a new renegotiated F&A rate was established with the National Institutes of Health ("NIH"). The new F&A rate for 2004 was 40%. The new F&A rate for 2005 was 30%. The result of this rate increase was an increase to the original grant of $5,173,298 to $6,433,316. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005.

Intangibles

We capitalize and amortize intangibles over a period of 11 to 16 years. Through September 30, 2005, intangibles have increased by approximately $313,000. This increase is attributed to payments made to legal firms that are engaged in filing and protecting our rights to our intellectual property and rights for our current products in both the domestic and international markets. The primary increase was attributed to our botulinum toxin programs.

Material Changes in Results of Operations—September 30, 2005 Compared to September 30, 2004

We are a research and development company. The 2005 revenues and associated expenses were from an NIH Grant which we received in September 2004. The 2004 revenues and associated expenses resulted from a Small Business Innovation Research (SBIR) grant we received in September 2003. Both grants were for further research associated with our ricin vaccine. The original amount of the NIH grant was $5,173,298. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a new renegotiated F&A rate with the NIH. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005. This new rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded.

On September 23, 2005 we were awarded a grant entitled "Oral BDP for the Treatment of GI GVHD" from the Food and Drug Administration. We will begin recognizing revenue for this grant beginning in the fourth quarter of 2005. The total amount of the one year grant is $318,750.

For the three months ended September 30, 2005 we had grant revenues of $733,892 as compared to zero in the three months ended September 30, 2004. For the nine months ended September 30, 2005, we had grant revenues of $2,370,135, an increase of $2,304,040, as compared to revenues of $66,095 for the same period in 2004. The 2005 revenue includes $285,891 that was attributed to the NIH reimbursement for overhead expenses for 2004 in the second quarter of 2005.

Our cost of revenues for the three months ended September 30, 2005 was $545,812 compared to zero for the three months ended September 30, 2004. For the nine months ended September 30, 2005, the cost of revenues was $1,465,664, an increase of $1,406,178, as compared to cost of revenues of $59,486 for the same period in 2004. These costs relate to payments made to subcontractors and universities in connection with the grants.

Although we have a gross profit, the gross profit is a result of the increase in the NIH award for a higher and more comprehensive F&A rate to provide for overhead expenditures. In addition, the gross profit of $188,080 and $804,471, for the three months and nine months ended September 30, 2005, respectively, includes $285,891 from 2004, as reimbursement in the second quarter of 2005 for the new F&A rate.

Research and development spending decreased $70,014, or 8%, to $964,398, for the three months ended September 30, 2005 as compared to $894,384 for the corresponding period ended September 30, 2004. Research and development expenses decreased $152,142, or 6%, to $2,431,289, for the nine months ended September 30, 2005, compared to $2,583,431 for the corresponding period ended September 30, 2004. In 2004, we incurred higher costs for research and development due to the completion of the pivotal Phase III clinical trial for orBec®. However, in the third quarter of 2005 our research and development costs showed an increase as compared to the same period in 2004. This was due to the increased regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®.

General and administrative expenses decreased $84,673, or 16%, to $441,489 for the three months ended September 30, 2005, as compared to $526,162 for the corresponding period ended September 30, 2004. General and administrative expenses decreased $296,063, to $1,207,297, or 20%, for the nine months ended September 30, 2005, compared to $1,503,360, for the nine months ended September 30, 2004. For the three months ended September 30, 2004 we had severance payments and accrued severance due former employees approximating $160,000. For the nine months ended September 30, 2005, the decrease was primarily attributed to a recovery of $284,855 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that have exceeded the number of allowed stock options under the plan.

Interest and other income for the three months ended September 30, 2005 was $19,989 as compared to $16,514 for the three months ended September 30, 2004, representing an increase of $3,475 or 21%. Interest and other income for the nine months ended September 30, 2005 was $68,588, an increase of $13,231, or 24%, as compared to $55,357 for the same period in 2004. This increase was primarily due to an increase in the number of days of available interest bearing cash balances in 2005 as compared to 2004.

Interest expense for the three months ended September 30, 2005 was a $39,567 credit as compared to $2,379 expense for the three months ended September 30, 2004, an increase of $41,946 or 1,763%. Interest expense for the nine months ended September 30, 2005 was a $36,549 credit as compared to $17,027 expense for the nine months ended September 30, 2004, an increase of $53,576 or 315%. This decrease in the interest expense was due to recovery of interest because of an agreement reached with a pharmaceutical company for settlement of a note payable. This agreement required a payment of $41,865 in lieu of the $83,729 of interest we had accrued.

For the three months ended September 30, 2005, we had a net loss applicable to common shareholders of $1,158,251 as compared to a $1,406,411 net loss applicable to common shareholders for the three months ended September 30, 2004, which represents a decrease of $248,160, or 18%. For the nine months ended September 30, 2005, we had a net

loss of $2,728,978, which represents a decrease in net loss of $1,816,069, or 40%, as compared to a net loss of $4,545,047 for the same period in 2004. For the nine months ended September 30, 2005 the net loss applicable to common shareholders included the impact of preferred stock dividends, which was zero in 2005, as compared to $503,195 in 2004. The decrease in preferred stock dividends was due to the conversion of all outstanding Series C preferred stock to 1.25 million shares of common stock in March 2004.

Material Changes in Results of Operations—December 31, 2004 Compared to December 31, 2003

For the year ended December 31, 2004 we had grant revenue of $997,482 as compared to $83,817 in the 12 months ended December 31, 2003. We also incurred expenses related to that revenue in 2004 and 2003 of $936,636 and $76,197, respectively. This revenue and associated expense was due to a National Institute of Health (NIH) Grant we received in September 2004 and a Small Business Innovation Research (SBIR) grant we received in September 2003 to further research associated with our ricin vaccine. The total amount of the NIH grant was $5,173,298 and the SBIR grant was $149,912.

For the 12 months ended December 31, 2004, we had a net loss applicable to common stockholders of $6,374,769 as compared to a $6,225,476 net loss applicable to common stockholders for the 12 months ended December 31, 2003, an increase of $149,293, or 2%. Net loss applicable to common stockholders included the impact of preferred stock dividends, which totaled $503,195 in 2004, as compared to $936,945 in 2003. The decrease in preferred stock dividends was due to the conversion of all outstanding Series C preferred stock to 1.25 million shares of common stock in November 2002.

The 2004 results reflect a continued shift of research and development (R&D) activities from in-house proprietary research and development activities to outsourced R&D that began in 2003. During 2004, our research and development spending increased to $3,656,776 as compared to $2,729,430 for 2003; an increase of $927,346 or 34% as compared to 2003. This increase was a result of a completion of the Phase III clinical trial for orBec® and the expenses related to our sponsored research programs for our ricin and botulinum programs.

General and administrative expenses for the 12 months ended December 31, 2004 were $2,321,186 as compared to $2,505,071 for the 12 months ended December 31, 2003, a decrease of $183,885, or 7%. This increase is in part attributed to severance costs associated with several former employees.

We are required to perform an annual impairment test, which we will perform in the fourth quarter of each year. During the fourth quarter of 2004, we completed our annual impairment test and determined that our intangible assets, namely, our patents and licenses, were impaired by $6,215. The net book value of the intangible assets will be reviewed annually and whenever the possibility of impairment is indicated. Any resulting impairment will be recorded in the income statement in the period in which it is identified and quantified.

Interest income for the 12 months ended December 31, 2004 was $66,539 as compared to $28,707 for the 12 months ended December 31, 2003, an increase of $37,832 or 132%. This increase was primarily due to the increase available cash balances from the financing completed in the first quarter of 2004.

Interest expense for the 12 months ended December 31, 2004 was $21,522 as compared to $63,968 for the 12 months ended December 31, 2003, a decrease of $42,446 or 66%. The decrease was due to a reduction in accrued interest expense related to the decrease in the balance payable of our only note payable to a pharmaceutical company.

Financial Condition

As of September 30, 2005, we had cash and cash equivalents of $1,833,128 as compared to $2,332,190 as of December 31, 2004, and working capital of $1,432,542 as compared to $1,050,649 as of December 31, 2004.

For the nine months ended September 30, 2005, our cash used in operating activities was $3,607,924, compared to $3,529,120 for the nine months ended September 30, 2004.

We expect our research and development expenditures for 2005, under existing product development agreements and license agreements pursuant to letters of intent and option agreements, to approximate $3,600,000. We anticipate grant revenues to offset research and development expenses of our ricin vaccine in the amount of approximately $2,500,000, pending completion of certain milestones.

As of September 30, 2005, we paid a note due of $115,948, which represents the remaining amount payable to a pharmaceutical company in connection with our joint ventures.

The following summarizes our contractual obligations at September 30, 2005, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	**Year 2005**	**Year 2006**
Non-cancelable obligations (1)	$ 66,914	$ 52,628
TOTALS	**$ 66,914**	**$ 52,628**

(1) 3 year lease on corporate office entered into in 2003 and expiring in 2006.

In February 2005, we increased our cash position by the issuance and sale of 8,396,100 shares of our common stock at $0.45 per share in a private placement to institutional investors. Such investors also received warrants to purchase 6,297,075 shares of our common stock at an exercise price of $0.505 per share. The proceeds after related expenses and closing costs were approximately $3.5 million.

Based on our current rate of cash outflows, and assuming availability of the Fusion facility, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the first quarter 2007. However, if the Fusion facility were not available, within the next two to three months we will be required to raise cash in order to meet cash flow requirements for the next year and to avoid going concern considerations. It is possible that within the upcoming 9 months we will seek additional capital in the private and/or public equity markets to support our operations, to respond to competitive pressures, to develop new products and services and to support new strategic partnerships. We may obtain capital pursuant to one or more corporate partnerships relating to orBec®. If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms or at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

DIRECTORS AND EXECUTIVE OFFICERS

The following table contains information regarding the current members of our Board of Directors and executive officers:

Name	Age	Position
Alexander P. Haig, J.D.	53	Chairman of the Board
Steve H. Kanzer, C.P.A., J.D.	42	Vice Chairman of the Board
James S. Kuo, M.D., M.B.A.	41	Director
T. Jerome Madison, C.P.A., M.B.A.	65	Director
Evan Myrianthopoulos	41	Chief Financial Officer and Director
Michael T. Sember, M.B.A.	56	Chief Executive Officer, President and Director
James Clavijo, C.P.A., M.A	40	Controller, Treasurer and Corporate Secretary

Alexander P. Haig, J.D., has been a director since 2004 and currently serves as our non-employee Chairman of the Board. Since 1988, Mr. Haig has served as the managing director of Worldwide Associates, Inc., a firm representing multi-national corporations and early stage development companies in marketing and business strategies. From 1992 to 1996, Mr. Haig also served as president of US-CIS Ventures, a privately held company active in transactions and projects in China and the former Soviet Union. From 1999 to 2002, Mr. Haig also served as Chairman and CEO of Sky Station International, Inc., a privately held telecommunications company. Mr. Haig has worked on a wide variety of projects for Worldwide Associates with particular emphasis on aerospace and pharmaceutical technologies and was active in providing strategic and financial advice to a broad range of companies from early stage through initial public offerings, including America Online, Inc. Previously a partner in a large private law firm, Mr. Haig concentrated on international trade and corporate matters. He received his undergraduate and law degrees from Georgetown University.

Steve H. Kanzer, C.P.A., J.D., has been a director since 1996 and currently serves as the non-executive Vice Chairman of the Board. Mr. Kanzer served as our Interim President from June 30, 2002 through January 4, 2003. Since December 2000, he has served as Chairman of Accredited Ventures Inc. and Accredited Equities Inc., respectively, a venture capital firm and NASD member investment bank specializing in the biotechnology industry. He also serves as President and/or a member of the board of directors of several private biopharmaceutical companies, including Pipex Therapeutics, Solovax, Inc., General Fiber, Inc., Effective Pharmaceuticals, Inc. and CD4 Biosciences, Inc.., each of which are involved in the licensing and development of clinical stage investigational new drugs and life science technologies. Since September 2004, he assumed the role as Chairman and Chief Executive Officer of Pipex Therapeutics, Inc., a biopharmaceutical company located in Ann Arbor, Michigan focusing on late stage products. From January 2001 until October 2003, Mr. Kanzer also served as President of Developmental Therapeutics, Inc. until its acquisition by Titan Pharmaceuticals, Inc. in October 2003. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer was a co-founder of Paramount Capital, Inc. in 1992 and served as Senior Managing Director - Head of Venture Capital of Paramount Capital until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies, including our company as well as a private biopharmaceutical company, Corporate Technology Development, Inc. ("CTD"). Mr. Kanzer was full-time Chief Executive Officer of CTD from March 1998 until December 2000 and part-time Chief Executive Officer from December 2000 until our company completed its acquisition of CTD in November 2001. From 1995 until June 1999, Mr. Kanzer was a founder and Chairman of Discovery Laboratories, Inc., a public biotechnology company. From 1997 until 2000, he was President of PolaRx Biopharmaceuticals, Inc. a biopharmaceutical company that licensed and developed TRISENOX®, a leukemia drug

currently marketed by Cephalon, Inc.. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York. Mr. Kanzer received his J.D. from New York University School of Law and a B.B.A. in accounting from Baruch College.

James S. Kuo, M.D., M.B.A., has been a director since 2004. Since January 2003, Dr. Kuo was a founder, and currently serves as Chairman and Chief Executive Officer of BioMicro Systems, a private nanotechnology company. Formerly, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories, Inc. from January 2002 to December 2002, where he raised over $22 million in initial private funding and successfully took the company public. Prior to that, he served as Vice President Business Development, from 2001 to 2002, of Metabasis, Inc. From 2000 to 2001, Dr. Kuo served as Vice President Worldwide Business Development of Genset Corporation. He has held senior business development positions at Pfizer, and Myriad Genetics. Dr. Kuo has also been Managing Director of Venture Analysis at HealthCare Ventures and Vice President at Paramount Capital Investments. Dr. Kuo is also a founder and former director of ArgiNOx, a private cardiovascular drug development company. Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

T. Jerome Madison, C.P.A., M.B.A., has been a director since May 2005 and is currently a General Partner at Founders Court, a company specializing in management buyouts of companies with significant growth potential. From 1982 to 1986, he was a co-founder and Chief Financial Officer of Cytogen, a cancer biotechnology company. From 1977 to 1982, he was with Rhone Poulenc Rorer (n/k/a Sanofi-Aventis), a major international pharmaceutical company, where he held the position of Corporate Controller and Chief Accounting Officer. Prior to that, Mr. Madison held financial positions at Abbott Laboratories and KPMG. Prior to joining KPMG, Mr. Madison served in the U.S. Navy as a Naval Flight Officer. Mr. Madison is a Certified Public Accountant and received his B.S. from Wharton School of the University of Pennsylvania and his M.B.A. from Monmouth University.

Evan Myrianthopoulos, has been a director since 2002 and is currently the Chief Financial Officer after joining the Company in November of 2004 as President and Acting Chief Executive Officer. Formerly he was President and founder of CVL Advisors, Group, Inc., from November 2001 to November 2004, a financial consulting firm specializing in the biotechnology sector. Prior to founding CVL Advisors Group, Inc., Mr. Myrianthopoulos was a co-founder of Discovery Laboratories, Inc., from June 1996 to November 2001, a public specialty pharmaceutical company developing respiratory therapies. While at Discovery, Mr. Myrianthopoulos held the positions of Chief Financial Officer and Vice President of Finance, where he was responsible for raising approximately $55 million in four private placements. He also negotiated and managed Discovery's merger with Ansan Pharmaceuticals and Acute Therapeutics. Prior to co-founding Discovery, Mr. Myrianthopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm. Prior to joining Paramount Capital, Mr. Myrianthopoulos was a managing partner of S + M Capital Management, a hedge fund which specialized in syndicated stock offerings and also engaging in arbitrage of municipal and mortgage bonds. Prior to that, Mr. Myrianthopoulos held senior positions in the treasury department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr. Myrianthopoulos holds a B.S. in Economics and Psychology from Emory University.

Michael T. Sember, M.B.A., became the Company's Chief Executive Officer, President and Director in December 2004. Mr. Sember brings 30 years of broad experience working with both public and private pharmaceutical and biotech companies in the U.S. and Europe. Mr. Sember has an extensive business development, operating and financial background which includes involvement with nearly 100 licensing transactions and several corporate acquisitions. Formerly he was Managing Director of EGB Advisors, LLC from December 2003 to December 2004, a business consulting firm and biotech incubator. Prior to joining EGB Advisors, LLC he was President and Chief Operating Officer of Women First Healthcare, from September 2003 to December 2003, a specialty pharmaceutical company. Prior to joining Women First Healthcare, he was President and Chief Operating Officer of Deltagen, Inc., from April 2002 to December 2002, a genomics company. Both Women's First Healthcare and Deltagen filed bankruptcy petitions subsequent to Mr. Sember's tenure at each company. Mr. Sember was not a member of the

executive management or an employee of either company during the period leading up to their engagement of him to assist in their efforts to accomplish a restructuring of their business. Prior to joining Deltagen, Inc. he was Executive Vice President of Business Development with Élan Corporation, from September 1991 to March 2002. At Élan he was responsible for building a strategic alliance portfolio, which included over 30 products in clinical development across several therapeutic areas including neurology, oncology, and pain management. During this period he generated approximately $900 million in licensing revenue during the development of the alliance portfolio. While at Élan he was also responsible for managing an investment portfolio valued at approximately $1.25 billion. In addition to this experience Mr. Sember has served on the Boards of eight public and private biotech companies and on the Advisory Boards of several venture capital firms, and currently serves on the board of Directors of Iomed Inc., a publicly traded company. Mr. Sember received a bachelor's degree from the University of Pittsburgh and a Master of Business Administration degree from Rockhurst University.

James Clavijo, C.P.A., M.A. Mr. Clavijo joined our company in October 2004 and is currently our Controller, Treasurer, and Corporate Secretary. He brings 15 years of senior financial management experience, involving both domestic and international entities, and participating in over $100 Million in equity and debt financing. Prior to joining DOR, Mr. Clavijo, held the position of Chief Financial Officer for Cigarette Racing Team (Miami, FL), from July 2003 to October 2004. During his time with Cigarette he was instrumental in developing a cost accounting manufacturing tracking system and managed the administration and development of an IRB Bond related to a 10 acre, 100,000 square foot facility purchase. Prior to joining Cigarette Racing Team, Mr. Clavijo held the position of Chief Financial Officer for Gallery Industries, from November 2001 to July 2003, a retail and manufacturing garment company. Prior to joining, Gallery, he served as Corporate Controller, for A Novo Broadband, from December 2000 to November 2001, a repair and manufacturing telecommunications company where he managed several mergers and acquisitions and corporate restructuring. Prior to joining A Novo Broadband, he served as Chief Financial Officer of AW Industries, from August 1997 to December 2000, a computer parts manufacturer. He also, held the position of Finance Manager for Wackenhut Corporation in the U.S. Governmental Services Division. In addition, he served in the U.S. Army from 1983 to 1996 in both a reserve and active duty capacity for personnel and medical units. Mr. Clavijo holds a Master in Accounting degree from Florida International University, a Bachelor in Accounting degree from the University of Nebraska, and a Bachelor in Chemistry degree from the University of Florida. Mr. Clavijo is a licensed Certified Public Accountant in the state of Florida.

EXECUTIVE COMPENSATION

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2003, 2004 and 2005, to the person who served as our Chief Executive Officers, and each of our two other executive officers during 2005 (collectively, the "Named Executive Officers").

Summary Compensation Table

Name	Position	Years	Annual Salary	Annual Bonus	Long term Compensation Awards Securities Underlying Options
Michael Sember (1)	CEO	2005	$300,000	$100,000	0
		2004	$20,000	--	2,000,000
Evan Myrianthopoulos (2)	CFO	2005	$185,000	$50,000	0
		2004	$25,694	--	650,000
James Clavijo (3)	Controller	2005	$125,000	$25,000	150,000
		2004	$27,500	--	100,000

(1) Mr. Sember joined in December 2004. Mr. Sember deferred payment of half of his 2005 annual bonus or $50,000.

(2) Mr. Myrianthopoulos joined in November 2004 as President and Acting Chief Executive Officer and then in December 2004 he accepted the position of Chief Financial Officer. Mr. Myrianthopoulos deferred payment of half of his 2005 annual bonus or $25,000.

(3) Mr. Clavijo joined in October 2004.

Option Grants in Last Fiscal Year

The following table contains information concerning options granted to the Named Executive Officers during the fiscal year ended December 31, 2005. We have never issued Stock Appreciation Rights.

Named Executive Officer	Number of Securities Underlying Options Granted	Percentage of Total Options Granted to Employees in Fiscal Year (1)	Exercise Price ($/share)(2)	Expiration Date
Michael Sember	0	N/A	N/A	N/A