DOR BIOPHARMA INC
Form 424B3
March 08, 2006

Filed Pursuant to Rule 424 (b)(3)
Registration No.: 333-131166

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

Table of Contents

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
Evan Myrianthopoulos	0	N/A	N/A	N/A
James Clavijo (3)	150,000	30%	$0.45	2/22/2015

(1) Based on options to purchase an aggregate of 500,000 shares of our common stock granted to employees and non-employee board members in the fiscal year ended December 31, 2005, including all options granted to the Named Executive Officers in all capacities in the fiscal year ended December 31, 2005.

(2) The exercise price of each grant is equal to the fair market value of the company's common stock on the date of the grant.

(3) Mr. Clavijo's options vested 50,000 on date of grant, February 22, 2005, with the balance vesting every three months from grant date, at a rate of 8,333 options per three month period.

Fiscal Year-End Option Table

The following table provides information on the total number of exercisable and unexercisable stock options held at December 31, 2005 by the Named Executive Officers. None of the Named Executive Officers exercised any options during fiscal year 2005.

Fiscal Year-End Option Values

	Number of Securities Underlying Unexercised Options at Fiscal Year-End (#)		Value of Unexercised In-the-Money Options at Fiscal Year-End(1) ($)	
Named Executive Officer	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable**
Michael Sember	1,120,000	880,000	N/A	N/A
Evan Myrianthopoulos	316,668	333,332	N/A	N/A
James Clavijo	108,332	141,668	N/A	N/A

(1) Based on the difference between the option's exercise price and a closing price of $0.27 for the underlying common stock on December 31, 2005 as reported by the American Stock Exchange. All options have an exercise price greater than $0.27 and thus were assigned no value.

Employment and Severance Agreements

During February 2005, we entered into a three year employment agreement with James Clavijo. Pursuant to this employment agreement we agreed to pay Mr. Clavijo a base salary of $125,000 per year. After one year of service Mr. Clavijo would be entitled to a minimum annual bonus of $25,000. We agreed to issue him options to purchase 150,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. This option grant is subject to stockholder approval of the 2005 Plan. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Clavijo three months severance subject to setoff, as well as any unpaid bonuses and accrued vacation. No unvested options shall vest beyond the termination date. Mr. Clavijo also received 100,000 options, vesting over three years when he was hired in October 2004, as Controller, Treasurer and Corporate Secretary.

During December 2004, we entered into a three year employment agreement with Evan Myrianthopoulos. Pursuant to this employment agreement we agreed to pay Mr. Myrianthopoulos a base salary of $185,000 per year. After one year of service Mr. Myrianthopoulos would be entitled to a minimum annual bonus of $50,000. We agreed to issue him options to purchase 500,000 shares of our common stock, with the options vesting over three years. This option grant is subject to stockholder approval of the 2005 Plan. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Myrianthopoulos six months severance subject to setoff, as well as any unpaid bonuses and accrued vacation. No unvested options shall vest beyond the termination date. Mr. Myrianthopoulos also received 150,000 options, vested immediately when he was hired in November 2004, as President and Acting Chief Executive Officer.

During December 2004, we entered into a three year employment agreement with Michael T. Sember, M.B.A. Pursuant to this employment agreement we agreed to pay Mr. Sember a base salary of $300,000 per year. After one year of service Mr. Sember would be entitled to a minimum annual bonus of $100,000. We agreed to issue him options to purchase 2,000,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. This option grant is subject to stockholder approval of the 2005 Plan. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Sember six months severance, as well as any unpaid bonuses and accrued vacation. No unvested options shall vest beyond the termination date.

Director Compensation

Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors or its committees. Each director who is not a full-time employee is paid $2,000 for each board or committee meeting attended ($1,000 if such meeting was attended telephonically).

We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of the our Board of Directors who are not full-time employees receive an initial grant of fully vested options to purchase 50,000 shares of common stock, and subsequent annual grants of fully vested options to purchase 50,000 shares of common stock after re-election to our Board of Directors.

On November 10, 2004, we entered into a letter agreement with Alexander P. Haig, to serve as the Chairman of the Board of Directors. We agreed to issue to him options to purchase 1,000,000 shares of our common stock, with 500,000 vesting immediately and 500,000 vesting in one year. In addition, on November 10, 2004, we entered into a one year consulting agreement with Worldwide Associates, Inc., for a fee of $16,500 per month. Mr. Haig is the managing director of Worldwide Associates, Inc. and ret. General Alexander M. Haig, Jr. is its President.

On December 23, 2002, we entered into a letter agreement with ret. General Alexander M. Haig, Jr. to serve as the Chairman of the Board of Directors. We agreed to pay General Haig a retainer of $50,000 per year, and issued to him options to purchase 2,000,000 shares of our common stock. On November 10, 2004, following his resignation from the Board of Directors, the retainer portion of this agreement was terminated and General Haig was given three years in which to exercise his options.

RELATED PARTY TRANSACTIONS

In September 2003, we completed a private placement of our common stock at $0.79 per share realizing gross proceeds of $5,410,348. In addition to common stock, for each share purchased investors received a warrant to purchase an additional share of common stock exercisable at $0.8756 per share until the earlier of an average closing price of our common stock of $1.68 per share or September 15, 2008. Purchasers in this private placement, on the same terms and conditions as the other subscribers, included Steve H. Kanzer, a member of our Board of Directors, who purchased for $100,000, 125,628 shares of common stock and warrants exercisable at $0.79 per share to purchase an additional 125,628 shares. Accredited Equities, Inc., a broker-dealer owned solely by Mr. Kanzer received cash compensation of approximately $38,000, and warrants exercisable for five years at $0.8756 per share to purchase 150,752 shares of common stock were issued to an employee of Accredited Equities, Inc. (other than Mr. Kanzer) in consideration for placement services rendered as a selected dealer to the placement agent of this private placement.

In connection with our 2003 private placement, Evan Myrianthopoulos, one of our Directors acted as a selected dealer to introduce certain investors to our company. Mr. Myrianthopoulos received cash compensation of approximately $62,000 and 256,314 warrants to purchase shares of common stock exercisable for five years at $0.8756 per share.

In connection with our 2003 private placement, Paramount Capital, Inc., an investment bank associated with a stockholder owning over 5% of our common stock, acted as our placement agent and was paid cash compensation of approximately $380,000, was issued warrants to purchase 822,907 shares of our common stock exercisable for five

years at $0.8756 per share and received an extension for an additional five years on pre-existing warrants to purchase 2,108,708 shares of common stock at $1.82 per share.

In January 2003, in connection with our execution of definitive license agreements for our ricin and botulinum toxin vaccines, we issued to Accredited Ventures, Inc., a company solely owned by Mr. Kanzer, a member of our board of directors, 150,000 options to purchase our common stock exercisable at $0.58 per share and 150,000 options to purchase our common stock exercisable at $1.28 per share. Mr. Kanzer has requested that half of these options be redirected to an employee of Accredited Ventures, Inc.

See also the description of our consulting agreement with Worldwide Associates, Inc. set forth under "Director Compensation." Mr. Haig is the managing director and ret. General Alexander M. Haig, Jr. is the President of Worldwide Associates, Inc.

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the Common Stock as of February 3, 2006. The table reflects ownership by: (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them. Except as otherwise indicated, each stockholder's percentage ownership of our common stock in the following table is based on 50,872,504 as of February 3, 2006 shares of common stock outstanding.

Name of Beneficial Owner	**Shares of Common Stock Beneficially Owned**	**Percent of Class**
Silverback Asset Management, LLC (1)	3,885,000	7.09 %
SF Capital Partners (2)	3,817,046	7.00 %
Alexander P. Haig (3)	1,050,000	2.02 %
Steve H. Kanzer (4)	2,135,635	4.03 %
James S. Kuo (5)	155,000	*
T. Jerome Madison (6)	100,000	*
Evan Myrianthopoulos (7)	794,677	1.54 %
Michael T. Sember (8)	1,230,000	2.36 %
James Clavijo (9)	116,665	*
All directors and executive officers as a group (7 persons)	5,581,977	9.89 %

* Indicates less than 1%.

(1) Includes 1,665,000 shares of common stock issuable upon exercise of warrants until August 2010. Reference to this was as reported on Schedule 13G filed with the SEC on March 21, 2005. According to this Schedule 13G, Elliot Bossen may be deemed to be a beneficial owner of all of these shares as a result of acting as the sole managing member of Silverback, and Silverback Master Ltd. may be deemed the beneficial owner of 3,108,000 of these shares. The address for Silverback is 1414 Raleigh Road, Suite 250, Chapel Hill, NC 27517.

(2) Includes 1,139,387 shares of common stock beneficially owned by SF Capital Partners Ltd, 1,012,659 shares of common stock issuable upon exercise of warrants within 60 days and 1,665,000 shares of common stock issuable upon exercise of warrants until August 2010. Reference to this was as reported on Schedule 13G filed with the SEC on February 15, 2005. According to this Schedule 13G, Michael A. Roth and Brian J. Stark may be deemed to be beneficial owners of these shares as a result of their acting as managing members of Stark Offshore Management, LLC, which acts as investment manager and has sole power to direct the management of SF Capital. The address for SF Capital Partners Ltd. is 3600 South Lake Drive St. Francis, WI 53235.

(3) Consists of 1,050,000 options to purchase common stock within 60 days of February 3, 2006. The address of Mr. Haig is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(4) Includes 1,069,437 shares of common stock owned by Mr. Kanzer, 349,398 warrants to purchase shares of common stock and 716,800 options to purchase common stock within 60 days of February 3, 2006. The address of Mr. Kanzer is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(5) Includes 150,000 options to purchase common stock and 5,000 warrants to purchase shares of common stock within 60 days of February 3, 2006. The address of Dr. Kuo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(6) Includes 100,000 options to purchase common stock within 60 days of February 3, 2006. The address of Mr. Madison is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(7) Includes 608,335 options to purchase common stock and 186,342 warrants to purchase common stock within 60 days of February 3, 2006. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(8) Includes 1,230,000 options to purchase common stock within 60 days of February 3, 2006. The address of Mr. Sember is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(9) Includes 116,665 options to purchase common stock within 60 days of February 3, 2006. The address of Mr. Clavijo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

Equity Compensation Plan Information

In December 2005 our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005.

Plan Category	**Number of Securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-Average Exercise Price Outstanding options, warrants and rights**	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)**
Equity compensation plans approved by security holders (1)	10,214,339	$ 0.59	6,800,000
Equity compensation plans not approved by security holders	--	--	--
TOTAL	10,214,339	$0.59	6,800,000

(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Out Plan expired in 2005 and thus no securities remain available for future issuance under that plan.

THE FUSION TRANSACTION

General

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, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over a period of approximately 15 months, subject to earlier termination at our discretion. In our discretion under certain conditions, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. The purchase price of the shares of common stock will be equal to a price based upon the future market price of our common stock. 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 pursuant to this prospectus including 900,000 shares to be issued to Fusion Capital as the commitment fee and 62,500 shares to be issued to Fusion Capital as a partial expense reimbursement. In connection with entering into the agreement, we authorized the sale to Fusion Capital of 9,000,000 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.

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.

Purchase of Shares Under the Common Stock Purchase Agreement

Under the common stock purchase agreement, on each trading day Fusion Capital is obligated to purchase a specified dollar amount of our common stock. Subject to our right to suspend such purchases at any time, and our right to terminate the agreement with Fusion Capital at any time, each as described below, Fusion Capital shall purchase on each trading day during the term of the agreement $20,000 of our common stock. This daily purchase amount may be decreased by us at any time. We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above $20,000 unless our stock price is above $0.40 per share for five consecutive trading days.

The purchase price per share is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the average of the three lowest closing sale prices of our common stock during the twelve consecutive trading days ending on the trading day immediately prior to the date of a purchase by Fusion Capital.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

The following table sets forth the amount of proceeds we would receive from Fusion Capital from the sale of 9.0 million shares of our common stock offered by this prospectus at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of 9,000,000 Shares to Fusion Capital Under the Common Stock Purchase Agreement
$0.12	$1,080,000
$0.15	$1,350,000
$0.25	$2,250,000
$0.44(1)	$3,960,000
$0.50	$4,500,000
$0.66	$6,000,000

(1) Closing sale price of our common stock on February 6, 2006.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of 9.0 million shares of our common stock. We have the right to terminate the agreement without any payment or liability to Fusion Capital at any time, including in the event that all $6.0 million shares are sold to Fusion Capital under the common stock purchase agreement. 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 be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules.

Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price ("floor price") of $0.12. Fusion Capital does not have the right or the obligation to purchase shares of our common stock on any trading day that the market price of our common stock is below $0.12.

Our Right To Suspend Purchases

We have the unconditional right to suspend purchases at any time for any reason effective upon one trading day's notice. Any suspension would remain in effect until our revocation of the suspension.

Our Right To Increase and Decrease the Amount to be Purchased

Under the common stock purchase agreement, Fusion Capital has agreed to purchase on each trading day during a period of approximately 15 months, $20,000 of our common stock or an aggregate of $6.0 million. We have the unconditional right to decrease the daily amount to be purchased by Fusion Capital at any time for any reason effective upon one trading day's notice.

In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. First, in respect of the daily purchase amount, we have the right to increase the daily purchase amount as the market price of our common stock increases. Specifically, for every $0.10 increase in Threshold Price (as defined below) above $.30, we have the right to increase the daily purchase amount by up to an additional $5,000. For example, if the Threshold Price is $0.50 we would have the right to increase the daily purchase amount by up to an additional $10,000. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately

preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will be void.

In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day our shares in an amount up to $200,000, provided that our share price is above $0.60 during the ten trading days prior to that trading day. The price at which such shares would be purchased would be the lower of (i) the lowest Purchase Price (as defined above) during the previous fifteen trading days prior to the date that such purchase notice was received by Fusion Capital or (ii) the lowest sale price on the date such purchase notice was received by Fusion Capital. We may increase this amount to $400,000 and $600,000 if our share price is above $0.90 and $1.20, respectively, during the ten trading days prior to our delivery of the purchase notice to Fusion Capital. We may deliver multiple purchase notices; however at least ten trading days must have passed since the most recent non-daily purchase was completed. The daily purchases shall be suspended for ten (10) trading days each time any such notice is delivered.

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

- the effectiveness of the registration statement of which this prospectus is a part of lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereby and such lapse or unavailability continues for a period of five (5) consecutive trading days or for more than an aggregate of twenty (20) trading days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of three consecutive trading days;

- the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the New York Stock Exchange or the OTC Bulleting Board;

- the transfer agent's failure for five (5) trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the common stock purchase agreement;

- any material breach of the representations or warranties or covenants contained in the common stock purchase agreement or any related agreements which has or which could have a material adverse affect on us subject to a cure period of five (5) trading days;

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;

- a material adverse change in our business, properties, operations, financial condition or results of operations; or

- the issuance of an aggregate of 10,117,439 (or 19.99% of our current shares outstanding) shares to Fusion Capital under our agreement and we fail to obtain the requisite stockholder approval.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the common stock purchase agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Effect of Performance of the Common Stock Purchase Agreement on Our Stockholders

All shares registered in this offering will be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 15 months from the date of this prospectus. The sale of a significant amount of shares registered in this offering at any given time could cause the trading price of our common stock to decline and to be highly volatile. Fusion Capital may ultimately purchase all of the 9,000,000 shares of common stock registered in this offering, and it may sell some, none or all of the shares of common stock it acquires upon purchase. Therefore, the purchases under the common stock purchase agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right at any time for any reason to: (1) reduce the daily purchase amount, (2) suspend purchases of the common stock by Fusion Capital and (3) terminate the common stock purchase agreement.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the common stock purchase agreement.

Commitment Shares Issued to Fusion Capital

Under the terms of the common stock purchase agreement we have issued to Fusion Capital 450,000 shares of our common stock as a partial commitment fee upon entering into the agreement. Fusion Capital is also entitled to receive up to an additional 450,000 commitment shares. These additional commitment shares will be issued in an amount equal to the product of (x) 450,000 (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the dollar amount of the shares being purchased by Fusion Capital and the denominator of which is $6.0 million. Unless an event of default occurs these shares must be held by Fusion Capital until 15 months from the date of the common stock purchase agreement or the date the common stock purchase agreement is terminated or in the event that we cannot commence sales of stock to Fusion Capital prior to March 15, 2006.

No Variable Priced Financings

Until the termination of the common stock purchase agreement, we have agreed not to issue, or enter into any agreement with respect to the issuance of, any variable priced equity or variable priced equity-like securities unless we have obtained Fusion Capital's prior written consent.

SELLING STOCKHOLDER

The following table presents information regarding the selling stockholder. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us.

Selling Security Holders' Table

Name and Address of Security Holder	Common Shares Beneficially Owned Prior to Offering (1)	Total Number of Shares to be Registered (1)	Total Number of Shares held by Security Holder After Offering
Fusion Capital II, LLC (2) 22 Merchandise Mart Plaza Suite 9-112 Chicago, IL 60654	512,500	9,962,500	- 0 -

(1) We have issued 512,500 shares of our common stock to Fusion Capital as a partial commitment fee and partial expense reimbursement. Fusion Capital may acquire an additional 9,450,000 shares under the common stock purchase agreement. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

(2) Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and investment power over the Fusion Capital shares being offered under this prospectus.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholder. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to $6.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement. We intend to use the net proceeds from sales under the Common Stock Purchase Agreement as working capital to cover costs associated with the assembly and filing of the NDA for orBec®, other research and development expenses, and general overhead costs including salaries until such time, if ever, as we are able to generate a positive cash flow from operation.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder only for cash directly to one or more purchaser or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed.

The sale of the common stock offered by this Prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions;
- any combination of the foregoing methods of sale; and
- any other method permitted pursuant to applicable law.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholders and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Fusion Capital is an "underwriter" within the meaning of the Securities Act of 1933. Any broker-dealers or agents that are involved in selling the shares for the selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with such sales.

Neither we nor the selling stockholder can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholder, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this Prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Fusion Capital and related persons against specified liabilities, including liabilities under the Securities Act of 1933.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the common stock purchase agreement.

We have advised Fusion Capital that while it is engaged in a distribution of the shares included in this Prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this Prospectus.

This offering will terminate on the date that all shares offered by this Prospectus have been sold by the selling stockholder.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 155,000,000 shares of capital stock, of which 150,000,000 shares are common stock, par value $.001 per share, 4,600,000 shares are preferred stock, par value $.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $.05 per share and 200,000 shares are Series C Convertible Preferred Stock, par value $.05 per share. As of February 6, 2006, there were issued and outstanding 50,872,504 shares of common stock, options to purchase 10,264,339 shares of common stock and warrants to purchase 22,167,118 shares of common stock. The amount outstanding does not include 450,000 shares issued to Fusion as a partial commitment fee and 62,500 shares issued to Fusion as partial expense reimbursement. The amount outstanding also does not include the balance of the commitment fee to be issued to Fusion Capital.

Common Stock

Holders of our common stock are entitled to one vote for each share held in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting in the election of directors. Holders of common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the corporation, holders of common stock are to share in all assets remaining after the payment of liabilities. Holders of common stock have no pre-emptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. The rights of the holders of the common stock are subject to any rights that may be fixed for holders of preferred stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 4,600,000 shares of preferred stock with designations, rights, and preferences as may be determined from time to time by the board of directors. The board of directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock with dividend, liquidation, conversion, voting or other rights, including the right to issue convertible securities with no limitations on conversion, which could adversely affect the voting power or other rights of the holders of our common stock, substantially dilute a common stockholder’s interest and depress the price of our common stock.

No shares of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock are outstanding.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our common stock is traded on the American Stock Exchange under the symbol "DOR." The table below sets forth the high and low sales prices, as provided by the American Stock Exchange, in each quarter for the period from

January 1, 2003 through February 6, 2006. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

Period	Price Range	
	High	**Low**
Fiscal Year Ended December 31, 2003:		
First Quarter	$1.71	$0.47
Second Quarter	$1.37	$0.77
Third Quarter	$1.15	$0.50
Fourth Quarter	$0.90	$0.60
Fiscal Year Ended December 31, 2004:		
First Quarter	$1.58	$0.70
Second Quarter	$0.97	$0.53
Third Quarter	$0.65	$0.36
Fourth Quarter	$0.81	$0.41
Fiscal Year Ended December 31, 2005:		
First Quarter	$0.67	$0.35
Second Quarter	$0.42	$0.29
Third Quarter	$0.45	$0.32
Fourth Quarter	$0.36	$0.22
Fiscal Year Ended December 31, 2006:		
First Quarter (through February 6, 2006)	$0.69	$0.26

As of February 6, 2006, the last reported price of our common stock was $0.44 per share. We have approximately 1,073 registered holders of record.

Dividend Policy

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependant upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Section 102(b)(7) of the Delaware General Corporation Law allows companies to limit the personal liability of its directors to the company or its stockholders for monetary damages for breach of a fiduciary duty. Article IX of the Company's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Company as follows:

"A Director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary

damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Company's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

EXPERTS

The audited consolidated financial statements of DOR BioPharma, Inc. and subsidiaries included herein in the Registration Statement have been audited by Sweeney, Gates & Co., an independent registered public accounting firm, for the years ended December 31, 2004 and 2003 as set forth in their report appearing herein and elsewhere in the Registration Statement. Such financial statements have been so included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the shares of our common stock offered by the Selling Stockholder will be passed upon by the law firm of Edwards Angell Palmer & Dodge LLP, Fort Lauderdale, Florida.

INDEX TO FINANCIAL PAGES

DOR BIOPHARMA, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

DOR BioPharma, Inc.
Consolidated Balance Sheet
September 30, 2005
(Unaudited)

Assets	
Current assets:	
Cash and cash equivalents	**$ 1,833,128**
Accounts receivable	**390,685**
Prepaid expenses	**211,394**
Total current assets	**2,435,207**
Office and laboratory equipment, net	**42,682**
Intangible assets, net	**2,044,118**
Total assets	$ **4,522,007**
Liabilities and shareholders' equity	
Current liabilities:	
Accounts payable	$ **783,835**
Accrued compensation and other expenses	**218,830**
Total current liabilities	**1,002,665**
Shareholders' equity:	
Preferred stock, $.001 par value. Authorized 4,600,000 shares; none issued and outstanding	-
Common stock, $.001 par value. Authorized 100,000,000 shares; 50,612,504 issued and outstanding	**50,612**
Additional paid-in capital	**86,045,192**
Accumulated deficit	**(82,576,462)**
Total shareholders' equity	**3,519,342**
Total liabilities and shareholders' equity	$ **4,522,007**

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the three months ended September 30,
(Unaudited)

	2005	2004
Revenues:	**$ 733,892**	$ -
Cost of revenues	**(545,812)**	-
Gross profit	**188,080**	-
Operating expenses:		
Research and development	**964,398**	894,384
General and administrative	**441,489**	526,162
Total operating expenses	**1,405,887**	1,420,546
Loss from operations	**(1,217,807)**	(1,420,546)
Other income (expense):		
Interest and other income	**19,989**	16,514
Interest expense (note 5)	**39,567**	(2,379)
Total other income (expense)	**59,556**	14,135
Net loss	$ **(1,158,251)**	$ (1,406,411)
Basic and diluted net loss per share	$ **(0.02)**	$ (0.03)
Basic and diluted weighted average common shares outstanding	**49,399,734**	41,870,601

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the nine months ended September 30,
(Unaudited)

	2005	2004
Revenues:	**$ 2,370,135**	$ 66,095
Cost of revenues	**(1,465,664)**	(59,486)
Gross profit	**804,471**	6,609
Operating expenses:		
Research and development	**2,431,289**	2,583,431
General and administrative	**1,207,297**	1,503,360
Total operating expenses	**3,638,586**	4,086,791
Loss from operations	**(2,834,115)**	(4,080,182)
Other income (expense):		
Interest and other income	**68,588**	55,357
Interest expense (note 5)	**36,549**	(17,027)
Total other income (expense)	**105,137**	38,330
Net loss	**(2,728,978)**	(4,041,852)
Preferred stock dividends	**-**	(503,195)
Net loss applicable to common shareholders	$ **(2,728,978)**	$ (4,545,047)
Basic and diluted net loss per share applicable to common shareholders	$ **(0.06)**	$ (0.11)
Basic and diluted weighted average common shares outstanding	**49,399,734**	40,024,065

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the nine months ended September 30,
(Unaudited)

	2005	2004
Operating activities:		
Net loss	$**(2,728,978)**	$(4,041,852)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	**170,915**	270,827
Non-cash stock option compensation	**(284,855)**	104,528
Change in operating assets and liabilities:		
Accounts receivable	**352,302**	20,954
Prepaid expenses	**(151,790)**	86,439
Accounts payable	**(965,518)**	29,984
Total adjustments	**(878,946)**	512,732
Net cash used by operating activities	**(3,607,924)**	(3,529,120)
Investing activities:		
Acquisition of intangible assets	**(313,592)**	(303,334)
Purchases of equipment	**(11,191)**	(5,673)
Net cash used by investing activities	**(324,783)**	(309,007)
Financing activities:		
Net proceeds from issuance of common stock	**3,549,593**	3,039,564
Proceeds from exercise of options	**-**	61,972
Repayments of amounts due under line of credit and note payable	**(115,948)**	(243,119)
Net cash provided by financing activities	**3,433,645**	2,858,417
Net decrease in cash and cash equivalents	**(499,062)**	(979,710)
Cash and cash equivalents at beginning of period	**2,332,190**	4,117,540
Cash and cash equivalents at end of period	**$ 1,833,128**	$ 3,137,830
Supplemental disclosure of cash flow:		
Cash paid for interest	**$ 41,865**	$ 17,552
Non-cash transactions:		
Issuance of preferred stock dividend in kind	**$ -**	$ 503,195

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. BASIS OF PRESENTATION

These unaudited interim consolidated financial statements of DOR BioPharma, Inc. ("we" or "us") were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, we omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with our audited consolidated financial statements and their notes included in our annual report on Form 10-KSB for the year ended December 31, 2004. In our opinion, the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

2. NET LOSS PER SHARE

In accordance with accounting principles generally accepted in the United States, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during respective periods (excluding shares that are not yet issued). The effect of stock options, warrants and convertible preferred stock is antidilutive for all periods presented. There were options to purchase approximately 10.2 million and 9.0 million shares of our common stock outstanding at September 30, 2005, and 2004, respectively.

3. STOCK BASED COMPENSATION

We have stock-based employee compensation plans. SFAS No. 123, "Accounting for Stock-Based Compensation," encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. We have chosen to continue using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, in accounting for our stock option plans.

Had compensation cost been determined based upon the fair value at the grant date for awards under the stock option plans based on the provisions of SFAS No. 123, our pro forma net loss and net loss per share would have been as follows for the nine months ended:

	September 30,	
	2005	2004
Net Loss applicable to common shareholders		
As reported	**$(2,728,978)**	$(4,545,047)
Add stock-based employee compensation expense related to stock options determined under fair value method	**(340,327)**	(1,508,453)
Pro forma net loss according to SFAS 123	**$ (3,069,305)**	$ (6,053,500)
Net loss per share:		
As reported, basic and diluted	**$ (0.06)**	$ (0.11)
Pro forma, basic and diluted	**$ (0.06)**	$ (0.15)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.29 and $0.55 for 2005 and 2004, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 120% and 105% in 2005 and 2004, respectively and average risk-free interest rates in 2005 and 2004 of 3.96% and 4.00%, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is periodically remeasured as the options vest.

4. INTANGIBLE ASSETS

Patent costs, principally legal fees, are capitalized and, upon issuance of the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life. Licenses of technology with alternative future use are capitalized and are amortized on a straight-line basis over the shorter of the estimated useful life or the regulatory life. Licenses of technology with no alternative future use are expensed as incurred. The useful lives of our patent and license costs at September 30, 2005 ranged from 11 to 16 years. The following is a summary of patent and license assets:

	Weighted Average Amortization period (years)	**Cost**	**Accumulated Amortization**	**Net Book Value**
September 30, 2005	10.5	$ 2,924,786	$ 880,668	$ 2,044,188
December 31, 2004	10.6	$ 2,611,195	$ 728,741	$ 1,882,454

Amortization expense was $45,785 and $151,927 for the three months and nine months ended September 30, 2005, respectively. The amortization expense for the same three month and nine month period in 2004, was $41,316 and $225,459, respectively.

Based on the balance of the intangibles at September 30, 2005, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2005	$ 197,000
2006	177,000
2007	177,000
2008	177,000
2009	177,000

Impairment of Long-Lived Assets

Office and laboratory equipment, and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets or the business to which such assets relate. 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. Such analyses necessarily involve significant judgment. The Company did not recognize any impairment in the nine months ended September 30, 2005.

5. NOTE PAYABLE

	September 30, 2005	December 31, 2004
Note payable to pharmaceutical company	**-**	$ 115,948

On June 29, 2002, DOR and a pharmaceutical company signed an agreement for the dissolution of their joint ventures. Based on this agreement, DOR retained the joint venture entities, InnoVaccines and Newco. In connection with the settlement, the Company's balance of $2,042,833 due to joint ventures at December 31, 2001 was restructured into payments totaling $1,104,242: $524,500 paid immediately in cash and the remaining $579,742 payments of principal and interest of $231,897 were due on June 30, 2003, $231,897 on June 30, 2004 and $115,948 on December 30, 2004, respectively.

The note payable of $115,948 to a pharmaceutical company was paid in the third quarter of 2005. An agreement was reached with the pharmaceutical company whereby we paid the principal balance in full, but only paid 50% of the interest accrued as full and final payment. The total payment of principal and interest was $157,813. The agreement resulted in a recovery of interest of $41,864.

6. SIGNIFICANT CONCENTRATIONS

During the nine months ended September 30, 2005, the Company had one customer, the United States federal government. All revenues generated in the nine months ended September 30, 2005, were from one United States federal government grant from the National Institute of Health ("NIH").

7. BUSINESS SEGMENTS

The Company had two active segments for the nine months ended September 30, 2005 and 2004: BioDefense and BioTherapeutics. Summary data for the three months and nine months ended:

	For the three months ended September 30,	
	2005	2004
Net Revenues		
BioDefense	**$ 733,892**	$ -
BioTherapeutics	**-**	-
Total	**$ 733,892**	$ -
Income (Loss) from Operations		
BioDefense	**$ (390,617)**	$ (299,445)
BioTherapeutics	**(399,842)**	(441,280)
Corporate	**(427,348)**	(680,621)
Total	**$ (1,217,807)**	$ (1,420,546)
Amortization and Depreciation Expense		
BioDefense	**$ 39,119**	$ 16,889
BioTherapeutics	**9,819**	49,374
Corporate	**3,152**	1,414
Total	**$ 52,090**	$ 67,677

	September 30, 2005	December 31, 2004
Identifiable Assets		

BioDefense	**$ 2,008,034**	$ 2,192,097
BioTherapeutics	**471,770**	230,048
Corporate	**2,042,203**	2,645,570
Total	**$ 4,522,007**	$ 5,067,715

	For the nine months ended September 30,	
	2005	2004
Net Revenues		
BioDefense	**$ 2,270,135**	$ 66,095
BioTherapeutics	**-**	-
Total	**$ 2,270,135**	$ 66,095
Income (Loss) from Operations		
BioDefense	**$ (548,941)**	$ (857,213)
BioTherapeutics	**(991,535)**	(1,267,473)
Corporate	**(1,293,639)**	(1,955,496)
Total	**$ (2,834,115)**	$ (4,080,182)
Amortization and Depreciation Expense		
BioDefense	**$ 67,316**	$ 63,191
BioTherapeutics	**94,105**	201,836
Corporate	**9,494**	5,800
Total	**$ 170,915**	$ 270,827

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of DOR BioPharma, Inc.,

We have audited the accompanying consolidated balance sheets of DOR BioPharma, Inc. and subsidiaries at December 31, 2004 and 2003 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years ended December 31, 2004 and 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company, as of December 31, 2004 and 2003 and the results of its operations and its cash flows for the years ended in the periods December 31, 2004 and 2003, in conformity with United States generally accepted accounting principals.

Sweeney, Gates & Co.

/s/ Sweeney, Gates & Co.
Fort Lauderdale, Florida
February 16, 2005

F-

DOR BioPharma, Inc.
Consolidated Balance Sheets
December 31,

	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	**$ 2,332,190**	$ 4,117,539
Accounts receivable	**742,987**	20,954
Prepaid expenses	**59,604**	155,844
Total current assets	**3,134,781**	4,294,337
Office and laboratory equipment	**50,480**	60,795
Intangible assets	**1,882,454**	1,896,934
Total assets	**$ 5,067,715**	$ 6,252,066
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	**$ 1,668,958**	$ 211,587
Accrued royalties	**100,000**	320,000
Accrued compensation and other expenses	**199,226**	116,638
Notes payable	**115,948**	359,067
Total current liabilities	**2,084,132**	1,007,292
Shareholders' equity:		
Preferred stock, $.001 par value. Authorized 4,600,000 shares; none issued and outstanding		
Series B convertible preferred stock, $.05 par value. Authorized 200,000 shares and 126,488 outstanding in 2003, at liquidation value	**-**	12,648,768
Common stock, $.001 par value. Authorized 100,000,000 shares; 42,418,404 and 34,893,765 issued and outstanding, respectively	**42,218**	34,894
Additional paid-in capital	**83,216,533**	67,005,276
Accumulated deficit	**(79,847,471)**	(73,975,897)
	3,411,280	5,713,041
Less treasury stock (120,642 and 172,342, respectively)	**(427,697)**	(468,267)
Total shareholders' equity	**2,983,583**	5,244,774
Total liabilities and shareholders' equity	**$ 5,067,715**	$ 6,252,066

The accompanying notes are an integral part of these financial statements

F-

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the years ended December 31,

	2004	2003
Revenues	**$ 997,482**	$ 83,817
Cost of revenues	**(936,636)**	(76,197)
Gross profit	**60,846**	7,620
Operating expenses:		
Research and development	**3,656,776**	2,729,430
General and administrative	**2,321,186**	2,505,071
Total operating expenses	**5,977,962**	5,234,501
Loss from operations	**(5,917,116)**	(5,226,881)
Other incomes (expense):		
Interest income	**66,539**	28,707
Interest expense	**(21,522)**	(63,968)
Other income, net	**525**	(26,389)
Total other income (expense)	**45,542**	(61,650)
Net loss	**(5,871,574)**	(5,288,531)
Preferred stock dividends	**(503,195)**	(936,945)
Net loss applicable to common shareholders	**$(6,374,769)**	$(6,225,476)
Basic and diluted net loss per share applicable to common shareholders	**$ (0.16)**	$ (0.21)
Basic and diluted weighted average common shares outstanding	**40,626,621**	29,183,312

The accompanying notes are an integral part of these financial statements

F-

DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2004 and 2003

	Series B Convertible Preferred Stock		Common Stock		Common Stock to be Issued		Additional Paid-in Capital	Deficit	Treasur
	Shares	Stated Value	Shares	Par Value	Shares	Stated Value			Shares
Balance at January 1, 2003	117,118	$ 11,711,822	26,794,642	$ 26,795	375,498	$ 436,812	$ 61,315,985	$ (68,687,366)	172,342
Issuance of common stock, from private placement	-	-	6,796,912	6,797	-	-	4,718,038	-	-
Issuance of common stock other	-	-	40,974	41	-	-	-	-	-
Issuance of options issued in exchange for licenses	-	-	391,305	391	-	-	329,689	-	-
Amortization of unearned compensation	-	-	-	-	-	-	-	-	-
Issuance of shares from options or warrants	-	-	494,434	494	-	-	187,224	-	-
Preferred stock dividends	9,370	936,946	-	-	-	-	(936,946)	-	-
Release of shares to be issued	-	-	375,498	375	(375,498)	(436,812)	436,436	-	-
Non-cash compensation	-	-	-	-	-	-	954,850	-	-
Net loss	-	-	-	-	-	-	-	(5,288,531)	-
Balance, December 31, 2003	126,488	12,648,768	34,893,765	34,894	-	-	67,005,276	(73,975,897)	172,342
Issuance of common stock, from private placement	-	-	4,113,925	4,114	-	-	3,035,756	-	-
Conversion of preferred	(128,203)	(12,820,303)	2,886,438	2,886	-	-	12,817,417	-	-

stock to common stock										
Exercise of shares from options or warrants	-	-	377,976	378	-	-	104,269	-	-	
Preferred stock dividends	1,715	171,535	-	-	-	-	(171,535)	-	-	
Non-cash compensation	-	-	-	-	-	-	467,183	-	-	
Purchase of treasury stock	-	-	-	-	-	-	-	-	2000	
Treasury stock retired	-	-	(53,700)	(54)	-	-	(41,832)	-	(53,700)	
Net loss	-	-	-	-	-	-	-	(5,871,574)	-	
Balance, December 31, 2004	-	$ -	42,218,404	$ 42,218	-	$ -	$ 83,216,533	$ (79,847,471)	120,642	$

The accompanying notes are an integral part of these financial statements

F-

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the years ending December 31,

	2004	2003
Operating activities:		
Net loss	**$ (5,871,574)**	$ () 5,288,531
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	**302,449**	226,140
Non-cash stock compensation	**467,183**	1,004,998
Change in operating assets and liabilities:		
Accounts receivable	**(722,033)**	(20,954)
Prepaid expenses	**96,240**	(51,511)
Accounts payable	**1,457,371**	(78,897)
Accrued royalties	**(220,000)**	-
Accrued compensation and other expenses	**82,588**	(95,480)
Total adjustments	**1,463,798**	984,296
Net cash used by operating activities	**(4,407,776)**	(4,304,235)
Investing activities:		
Intangible assets	**(267,096)**	(353,116)
Purchases of equipment	**(10,559)**	(17,854)
Proceeds from assets sold or retired	**-**	103,407
Net cash used by investing activities	**(277,655)**	(267,563)
Financing activities:		
Net proceeds from issuance of common stock	**3,039,870**	4,724,849
Proceeds from exercise of options	**104,647**	187,224
Payments of long-term debt	**(243,119)**	(369,900)
Purchases of common stock for treasury	**(1,316)**	-
Net cash provided by financing activities	**2,900,082**	4,542,173
Net (decrease) in cash and cash equivalents	**(1,785,349)**	(29,625)
Cash and cash equivalents at beginning of period	**4,117,539**	4,147,164
Cash and cash equivalents at end of period	**$ 2,332,190**	$ 4,117,539
Supplemental disclosure of cash flow:		
Cash paid for interest	**$ 3,383**	$ 5,330

Non-cash transactions:

Non-cash stock options expense	**$ 393,913**	$ 1,004,998
Issuance of preferred stock dividend in kind	**$ 171,535**	$ 936,945
Issuance of common stock for intangible assets	**$ 32,778**	$ 320,000
Options for increase in subsidiary ownership	**$ 88,740**	$ -
Issuance of common stock to induce preferred stock conversion	**$ 331,660**	$ -

The accompanying notes are an integral part of these financial statements

F-

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Organization and Nature of Business

Principles of Consolidation

The consolidated financial statements include DOR BioPharma Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). The Company owns an 89.13% interest in Enteron Pharmaceuticals, Inc., its subsidiary developing orBec®. All significant intercompany accounts and transactions have been eliminated in consolidation.

Nature of Business

DOR is a biopharmaceutical company focused on the research and development of biodefense vaccines and therapeutics intended for areas of unmet medical need. Through the Company's biodefense division it is developing bioengineered vaccines designed to protect against the deadly effects of ricin toxin and botulinum toxin exposure, both of which are considered serious bioterrorism threats. In addition to the biodefense vaccines, the Company is developing orBec®, a potent locally-active corticosteroid, for the treatment of intestinal inflammation associated with acute Graft-versus-Host Disease (iGVHD) following allogeneic bone marrow transplant.

In the fourth quarter of 2004, the Company emerged from the development stage. Prior to the third quarter of 2004, the Company's activities were principally centered on raising capital and conducting research and development in conjunction with developing new products. In 2004, the Company earned $997,482 in revenue. The Company has developed into a biopharmaceutical company engaged in the research and development of vaccines and drugs. In 2004, the Company completed its pivotal Phase III clinical trial for its orBec® product. In addition, the Company has obtained a significant governmental grant for the development of a recombinant vaccine to protect against exposure from ricin toxin.

2. Summary of Significant Accounting Policies

Segment and Geographic Information

The Company had two active segments for the year ended December 31, 2004 and 2003: BioDefense and BioTherapeutics. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less when purchased to be cash equivalents.

Intangible Assets

Intangible assets consist of patent costs, principally legal fees, and, upon issuance of the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life. Licenses of technology with alternative future use are capitalized and are amortized on a straight-line basis over the shorter of the estimated useful life or the regulatory life.

Impairment of Long-Lived Assets

Office and laboratory equipment, and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets or the business to which such assets relate. 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. Such analyses necessarily involve significant judgment.

The Company recorded impairment of intangible assets of $6,215 and $59,340 for the years ended December 31, 2004 and 2003, respectively.

Fair Value of Financial Instruments

Accounting principles generally accepted in the United States require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, current liabilities and debt obligations, are considered to be representative of their respective fair values.

Government research grant revenue

The Company recognizes revenue from federal research grants during the period in which related expenditures are incurred.

Research and Development Costs

Research and development costs are charged to expense when incurred. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries and employee benefits, equipment depreciation and allocations of various corporate costs. Purchased in-process research and development expense (IPR&D) represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Stock Based Compensation

The Company has stock-based compensation plans. SFAS No. 123, "Accounting for Stock-Based Compensation," encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has chosen to continue using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, in accounting for its stock option plans. In December 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard SFAS No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure" which amends SFAS No. 123 "Accounting for Stock-Based Compensation." Had compensation cost been determined based upon the fair value at the grant date for awards under the plans based on the provisions of SFAS No. 123, the Company's SFAS No. 123 pro forma net loss and net loss per share would have been as follows:

	December 31,	
	2004	2003
Net loss applicable to common shareholders		
As reported	**$(6,374,769)**	$(6,225,476)

Add stock-based employee compensation expense related to stock options determined under fair value method	**(1,023,368)**	(919,282)
Deduct amounts charged to expense	**284,855**	645,850)
Pro forma net income according to SFAS 123	**$(7,113,282)**	$(7,498,908)
Net loss per share:		)
As reported, basic and diluted	**$(.16)**	$(.21
Pro forma, basic and diluted	**$(.18)**	$ (.25)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.44 and $0.30 for 2004 and 2003, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 129% and 185% in 2004 and 2003, respectively and average risk-free interest rates in 2004 and 2003 of 3.5% and 3.0%, respectively.

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and Emerging Issues Task Force (“EITF”) 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is periodically remeasured as the options vest.

Income Taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the current tax payable for the period plus or minus the change during the period in deferred tax assets and liabilities. No current or deferred income taxes have been provided through December 31, 2004 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods (excluding shares that are not yet issued). The effect of stock options, warrants and convertible preferred stock is antidilutive for all periods presented.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Risk and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

New Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, "Accounting For Certain Financial Instruments with Characteristics of both Liabilities and Equity". SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet.

SFAS No. 150 affects the issuer's accounting for three types of freestanding financial instruments. One type is mandatory redeemable shares, which the issuing company is obligated to buy back in exchange for cash or other assets. A second type includes put options and forward purchase contracts. This instrument involves instruments that do or may require the issuer to buy back some of its shares in exchange for cash or other assets. The third type of instruments that are liabilities under this Statement is obligations that can be settled with shares, the monetary value of which is fixed, tied solely or predominantly to a variable such as a market index, or varies inversely with the value of the issuers' shares. SFAS No. 150 does not apply to features embedded in a financial instrument that is not a derivative in its entirety.

Most of the provisions of SFAS No. 150 are consistent with the existing definition of liabilities in FASB Concepts Statement No. 6, "Elements of Financial Statements". The remaining provisions of this Statement are consistent with the FASB's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own shares. This Statement was effective for financial instruments entered into or modified after May 31, 2003. The adoption of this statement did not have any impact on the Company's financial position or the results of its operations.

In December 2003, the issued Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition," rescinded the accounting guidance contained in SAB No. 101, "Revenue Recognition in Financial Statements," and incorporated the body of previously issued guidance related to multiple-element revenue arrangements. The Company's adoption of SAB No. 104 did not have any impact on its consolidated financial statements.

In March 2004, the FASB ratified EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments" ("EITF 03-1"), but delayed the recognition and measurement provisions of EITF 03-1 in September 2004. For reporting periods beginning after June 15, 2004, only the disclosure requirements for available-for-sale securities and cost method investments are required. The Company's adoption of the requirements did not have a significant impact on the Company's disclosures.

In July 2004, the FASB issued EITF Issue No. 02-14, "Whether an Investor Should Apply the Equity Method of Accounting to Investments Other than Common Stock" ("EITF 02-14"). EITF 02-14 requires application of the equity method of accounting when an investor is able to exert significant influence over operating and financial policies of an investee through ownership of common stock or in-substance common stock. EITF 02-14 is effective for reporting periods beginning after September 15, 2004. The adoption of EITF 02-14 will not have a significant impact on the Company's consolidated financial statements.

On December 16, 2004, the FASB issued Statement No. 123R, "Share-Based Payment" which requires companies to record compensation expense for stock options issued to employees at an amount determined by the fair value of the options. SFAS No. 123R is effective for interim or annual periods beginning after June 15, 2005. As such, effective with the Company's first fiscal quarter of 2006, SFAS No. 123R will eliminate the Company's ability to account for stock options using the method permitted under APB 25 and instead require us to recognize compensation expense

should the Company issue options to its employees or non-employee directors. The Company is in the process of evaluating the impact adoption of SFAS No. 123R will have on the consolidated financial statements.

3. Office and Laboratory Equipment

Office and laboratory equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following:

	December 31,	
	2004	2003
Office equipment	**$ 95,417**	$ 84,857
Laboratory equipment	**23,212**	117,588
Total	**118,629**	202,445
Accumulated depreciation	**(68,149)**	(141,650)
	$ 50,480	$ 60,795

Depreciation expense was $20,875 and $90,185 for the years ended December 31, 2004 and 2003, respectively.

F-

4. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2004	10.6	$ 2,611,195	$ 728,741	$ 1,882,454
December 31, 2003	11.9	$ 2,351,955	$ 455,021	$ 1,896,934

Amortization expense was $302,449 and $135,955 for 2004 and 2003, respectively.

Based on the balance of licenses and patents at December 31, 2004, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2005	$ 257,000
2006	173,000
2007	173,000
2008	173,000
2009	173,000

In July 2003, the Company entered into an exclusive license agreement with University of Texas South Western for administering the ricin vaccine via the intramuscular route for initial license fees of 250,000 shares valued at $200,000 of our common stock and $100,000 in cash. Subsequently, in October 2004, the Company negotiated the remaining intranasal and oral rights to the ricin vaccine for additional license fees of $150,000 in cash. The Company license obligates $50,000 in annual license fees in subsequent years.

In October 2003, the Company executed an exclusive license agreement with the University of Texas System (UTMB) for the use luminally-active steroids, including beclomethasone dipropionate (BDP) in the treatment of irritable bowel syndrome. Pursuant to this agreement the Company paid UTMB a license fee of $10,000 and also agreed to pay an additional $10,000 license fee each year on the anniversary of this agreement. The Company also agreed to pay past and future patent maintenance costs. The cost for 2004 and 2003 was $39,171 and $7,830, respectively.

The Company acquired a sublicense agreement and may receive payments on this sublicense in the event of the sublicensee reaching certain milestones. The Company currently has capitalized $120,101 and it has a one year life remaining.

Upon execution of a royalty bearing license agreement to a pharmaceutical company in July 2003, the Company paid an additional license fee of $175,000. The Company also agreed to provide $125,000 of sponsored research during 2003, a $60,000 annual license fee and $60,000 annually for patent maintenance.

In May 2003, the Company signed a license agreement with Thomas Jefferson University (TJU) for the licensure of detoxified botulinum toxin for use as a vaccine, under this license the Company paid TJU $30,000 in cash and issued 141,305 shares of common stock valued at $130,000. The Company also agreed to reimburse TJU for past and future

patent maintenance. The patent maintenance expense for 2004 and 2003 was $58,922 and $92,835, respectively. The Company is also responsible for a license maintenance fee of $10,000 in 2004 and 2005 and $15,000 in 2005 and each year thereafter.

5. Notes Payable

Notes payable were as follows:

	December 31,	
	2004	2003
Note payable to pharmaceutical company	**$ 115,948**	$ 347,845
Note payable to a bank	**-**	11,222
Total	**$ 115,948**	$ 359,067

On June 29, 2002, DOR and a pharmaceutical company signed an agreement for the dissolution of their joint ventures. Based on this agreement, DOR retained the joint venture entities, InnoVaccines and Newco. In connection with the settlement, the Company's balance of $2,042,833 due to joint ventures at December 31, 2001 was restructured into payments totaling $1,104,242: $524,500 paid immediately in cash and the remaining $579,742 payments of principal and interest of $231,897 were due on June 30, 2003, $231,897 on June 30, 2004 and $115,948 on December 30, 2004, respectively.

The note payable to a pharmaceutical company was not paid as of its due date at the end of December 31, 2004. The note is in default.

The note payable to a bank was paid in full on January 15, 2004. Interest was at prime less .25% (4.0%) and borrowings were secured by a short-term certificate of deposit which is included in cash and cash equivalents.

6. Shareholders' Equity

Preferred Stock

In 1998, a pharmaceutical company purchased $8.0 million of DOR Series B convertible preferred stock, which was convertible into common stock at a price of $5.11 per share, subject to adjustment, with automatic conversion at such point that the common stock traded over 100,000 shares per day at a closing price of at least $9.75 per share for 20 out of 30 consecutive trading days. In the intervening years, the Company issued additional preferred shares and stock dividends. The Series B convertible preferred stock paid an 8% annual in-kind dividend, which was valued at $171,535 and $936,946 in 2004 and 2003, respectively. The Company issued 1715 and 9,349 shares of preferred stock respectively. In addition, the Company issued the pharmaceutical company 376,886 shares of common stock valued at $331,660, as an inducement for the early conversion. In March 2004, the Company exchanged 128,203 shares of Series B of preferred stock for 2,886,438 shares of common stock.

Common Stock

During 2004, individuals exercised common stock options and common stock warrants at various prices from $0.20 to $0.75 for total proceeds of $104,647.

In March 2004, the Company sold an aggregate of 4,113,925 shares of common stock in a private placement. Gross proceeds were $3,250,000 (net after commissions and expenses was $3,039,870). In addition to common stock, for each share purchased investors received a warrant to purchase .4 shares of common stock, for a total of 1,645,570, exercisable at $0.87 per share until the earlier of an average closing price for 20 consecutive days of the Company's

common stock of $1.74 per share or March 15, 2009. In connection with the 2004 private placement, the placement agent was paid cash compensation of approximately $162,500, and issued warrants to purchase 287,974 shares of the Company's common stock exercisable for five years at $0.87 per share.

In September 2004, the Company retired 53,700 shares of treasury stock.

In September 2003, the Company sold an aggregate of 6,796,912 shares of common stock in a private placement. Gross proceeds were $5,410,348 (net after commissions and expenses was $4,724,835). Commissions of approximately $100,000 were paid to related parties who were agents for the private placement. Investors in the September 2003 private placement also received warrants for the purchase of 6,796,919 shares of DOR common stock. The warrants issued to these investors were immediately exercisable at $0.8756 per share and expire September 15, 2008. Also, as part of the compensation received for its assistance in the private placement, the placement agents/dealers received warrants to purchase an aggregate 1,359,383 shares of DOR common stock. These warrants were immediately exercisable at $0.8756 per share and expire September 15, 2008. The Company has the right to call the warrants if the closing bid price of DOR's common stock equals or exceeds $2.62 per share for at least 20 consecutive days.

Stock Compensation to Non-employees

During 2004, the Company issued 46,886 warrants to purchase common stock valued at $32,778 to a University for license agreements.

During 2004, the Company issued 50,000 stock options to purchase common stock valued at $20,270 each, for a total of $60,810 to each of the resigning directors.

During 2004, the Company issued 200,000 warrants to purchase common stock valued at $88,740 to a consultant, in exchange for his 160,000 shares of Enteron stock. In addition, contingent warrants were issued to a consultant. A consultant was issued 400,000 warrants to purchase common stock for consulting services with an expiration date of April 2009 and will be exercisable on the approval date for orBec®.

In 2004 and 2003 the Company granted options to employees and directors that were conditional upon stockholder approval of an amendment to an 1995 Omnibus Option Plan. Accordingly, a measurement date did not exist at the approval date. The company needed expense of approximately $285,000 and $646,000, respectively.

During 2003, the Company issued 6,674 at market shares of common stock valued at $5,843 in settlement of a dispute with their former placement agent.

During 2003, the Company issued 392,000 at market shares of common stock valued at $330,000 to Universities for license agreements.

7. Stock Option Plans and Warrants

The Amended and Restated 1995 Omnibus Plan (the Plan) is divided into four separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

	December 31,	
	2004	2003
Shares available for grant at beginning of year	**1,630,587**	(817,300)
Increase in shares available	**-**	-
Amendment to increase shares available in plan	**-**	5,291,743
Options granted under the Plan	**(4,500,000)**	(4,520,000)
Options exercised	**240,000**	-
Options forfeited or expired	**650,074**	1,676,144
Shares available for grant at end of year	**(1,979,339)**	1,676,144

In 2004 and 2003, the Company granted options to employees and directors that were conditional upon stockholder approval of an amendment to the 1995 omnibus stock option plan. Accordingly, a measurement date did not exist at that approval date. The Company recorded an expense of approximately, $285,000 and $646,000, respectively.

F-

Option activity for the years ended December 31, 2004 and 2003 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at December 31, 2002	5,469,611	$ 0.95
Granted	4,520,000	0.80
Forfeited	(1,676,144)	1.85
Exercised	(424,054)	0.39
Balance at December 31, 2003	**7,889,413**	**0.72**
Granted	4,500,000	0.49
Forfeited	(650,074)	0.78
Exercised	240,000	0.20
Balance at December 31, 2004	**11,979,339**	**$ 0.64**

The weighted-average exercise price, by price range, for outstanding options at December 31, 2004 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.20-$0.50	5.86	6,860,000	4,440,000
$0.51-$1.00	3.06	4,577,839	4,059,505
$1.01-$6.00	4.89	541,500	541,500
Total	**4.55**	**11,979,339**	**9,041,005**

From time to time, The Company grants warrants to consultants and grants warrants in connection with private placements. The weighted-average exercise price, by price range, for outstanding options at December 31, 2004 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.35-$0.75	3.32	2,699,606	2,699,606
$0.76-$1.50	3.81	10,089,847	10,089,847
$1.51-$8.50	2.82	2,898,265	2,898,265
Total	**3.54**	**15,687,718**	**15,687,718**

F-

8. Income Taxes

The types of temporary differences between tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax asset (liability) and their approximate tax effects are as follows:

	December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	**$ 21,524,000**	$ 22,893,000
Research and development credit carryforwards	**693,000**	1,988,000
Work opportunity credit carryforwards	**260,000**	260,000
Orphan drug credit carryforwards	**1,894,000**	2,595,000
Total	**24,371,000**	27,736,000
Valuation allowance	**(24,371,000)**	(27,736,000)
Net deferred tax assets	**$ -**	$ -

At December 31, 2004, the Company had net operating loss carryforwards of approximately $54.2 million for Federal and state tax purposes, which began to expire in 2004.

The following is the approximate amount of the Company's net operating losses that expire over the next five years:

9. Commitments and Contingencies

Office lease commitments

The Company leases its corporate offices under an operating lease which expires September 2006, and provides for annual minimum rent and additional rent based on increases in operating costs and real estate taxes. Rent expense was $70,999 in 2004 and $74,110 in 2003.

2005	$ 544,000
2006	222,000
2007	981,000
2008	910,000
2009	1,609,000

Future minimum lease payments under the non-cancelable operating lease will be:

	Lease Payments
2005	$ 66,914
2006	52,628

F-

10. Significant Concentrations

During the year ended December 31, 2004, the Company had one customer, the U.S. Federal Government. All revenue generated in the year ended December 31, 2004 came from two U.S. Federal Government Grants. As of December 31, 2004 all outstanding receivables were from the U.S. Federal Government, National Institute of Health

During the year ended December 31, 2004, the Company had one vendor that made up 38% of the outstanding payables.

11. Subsequent Events (Unaudited)

Private Placement

On February 9, 2005, the Company closed a private equity financing with certain institutions and accredited investors. The Company issued 8,396,100 shares of common stock at a price of $0.45 and warrants to purchase 6,247,075 shares of common stock at a price of $0.505 per share. The Company also issued the placement agent, a warrant to purchase 629,708 shares of common stock at a price of $0.625 per share. The gross proceeds to the Company were approximately $3.77 million.

12. Business Segments

The Company had two active segments for the year ended December 31, 2004 and 2003: BioDefense and BioTherapeutics. Summary data:

	December 31,	
	2004	2003
Net Revenues		
BioDefense	**$ 997,482**	$ 83,817
BioTherapeutics	**-**	-
Total	**$ 997,482**	$ 83,817
Loss from Operations		
BioDefense	**$ (1,171,343)**	$ 1,098,125)
BioTherapeutics	**(2,424,587)**	(1,623,685)
Corporate	**(2,652,846)**	(2,505,071)
Total	**$-5,075,429)**	$-4,128,756)
Identifiable Assets		
BioDefense	**$2,192,097**	$ 1,361,362
BioTherapeutics	**230,048**	221,000
Corporate	**2,645,570**	4,669,704
Total	**$5,067,715**	$ 6,252,066
Amortization and Depreciation Expense		
BioDefense	**$ 117,001**	$ 85,000
BioTherapeutics	**169,264**	120,573
Corporate	**16,184**	20,567
Total	**$ 302,449**	$ 226,140