DOR BIOPHARMA INC
Form 10KSB
March 11, 2005

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

FORM 10-KSB

(Mark One)
[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the Fiscal Year Ended **December 31, 2004**

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from _____ to _____

Commission File No. 1-14778

DOR BIOPHARMA, INC.
(Name of small business issuer in its charter)

Delaware	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1691 Michigan Ave., Suite 435, Miami, FL	**33139**	**305-534-3383**
(Address of principal executive offices)	(Zip Code)	(Telephone number)

Securities registered under Section 12 (b) of the Exchange Act:

Title of Each Class of Securities to be Registered	Name of Each Exchange on Which Registered
Common Stock, par value $.001 per share	**American Stock Exchange**

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

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes [X] No [ ]**

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. **[ ]**

Issuer's revenues for its most recent fiscal year: **$997,482**

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $21,743,000, (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), based on the closing price of the registrant's common stock as reported on the American Stock Exchange on March 2, 2005.

At March 2, 2005, 50,612,504 shares of the registrant's common stock were outstanding.

Transitional Small Business Disclosure Format (check one): **Yes [ ] No [X]**

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PART I

Item 1. Description of Business.

This Annual Report on Form 10-KSB 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 report that could cause actual results to differ materially from those indicated in any forward-looking statements, including those set forth in "Risk Factors" in this Annual Report. See "Cautionary Note Regarding Forward Looking Statements."

A. Overview

We are a biopharmaceutical company focused on the research and development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. We were incorporated in 1987. We maintain two active segments; BioDefense and BioTherapeutics.

BioDefense Overview

Through our BioDefense Division, we are developing bioengineered countermeasure vaccines for ricin toxin and botulinum toxin, both of which are considered bioterrorism threats by the U.S. Department of Homeland Security (DHS), National Institute of Allergic and Infectious Diseases (NIAID), Department of Defense (DOD) and Centers for Disease Control and Prevention (CDC). We are developing our biodefense countermeasures for potential U.S. government procurement pursuant to the Project Bioshield Act of 2004, which provides incentives to industry to expeditiously supply biodefense countermeasures to the Strategic National Stockpile. As a step towards this goal, on September 13, 2004, we were awarded a $5.2 million grant from the National Institute of Allergy and Infectious Diseases (NIAID) for RiVax™, our genetically engineered vaccine against ricin toxin, one of the most lethal plant toxins known to man. The grants project period is September 15, 2004 to August 31, 2007 and covers the process development for manufacturing of RiVax™ our recombinant vaccine for ricin toxin. The grant is based on milestones and certain budget amounts are earned as we meet certain milestones in the development of RiVax™. In addition, on February 7, 2005, we announced that our academic partner, The University of Texas Southwestern Medical Center at Dallas, began a Phase I clinical trial of RiVax™ in normal volunteers. This is the first time a ricin toxin vaccine will be studied in humans. Also, on January 7, 2005, we announced an agreement with Cambrex corporation (NYSE: CBM) on the consummation of an agreement for the process development and potential large scale production of RiVax™ covered by the aforementioned grant.

Our vaccine against botulinum neurotoxin, one of the most lethal substances known to man, BT-VACC™, is an orally administered vaccine that protects against exposure to botulinum neurotoxins. As opposed to injectable vaccines that require multiple injections, BT-VACC™ is being developed as a multivalent, solid oral dosage form. BT-VACC™ is covered by issued and pending U.S. patents that broadly claim orally deliverable botulinum neurotoxin vaccines. The oral formulation is designed to be sufficiently stable for stockpiling and storage, which is ideal for rapid distribution and vaccination for military use or civilian vaccination in response to bioterrorism. Oral administration of BT-VACC™ for serotype A produces protective antibodies that afford protection or prolonged survival of treated animals exposed to 30,000 times the lethal dose of botulinum toxin serotype A. Pre-clinical studies of BT-VACC™ for serotype B are also ongoing. On February 16, 2005, we expanded our biodefense product line from prophylactic (pre-exposure) vaccines into post-exposure therapeutics when we initiated a rational drug design program intended to identify small molecules capable of blocking the deadly effects of botulinum toxin on a post-exposure basis.

BioTherapeutics Overview

Through our BioTherapeutics Division, we are in the process of developing oral therapeutic products to treat unmet medical needs. Our therapeutic product, orBec® (oral beclomethasone dipropionate), has recently completed a pivotal Phase III clinical trial for the treatment of acute intestinal graft-vs-host disease (iGVHD), a form of serious and life-threatening gastrointestinal inflammation. On December 30, 2004, we announced top line results of 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 it's 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 70% reduction in mortality compared to placebo (p-value 0.007). orBec® is a highly potent, topically-active glucocorticoid. orBec® has previously been granted Fast Track Designation and received Orphan Drug Designation by the Food and Drug Administration (FDA) for the treatment of iGVHD. We are

currently in discussions with the FDA to determine the next steps for orBec® and pending the outcome of these discussions, expect to be in a position to offer guidance in second quarter 2005.

B. 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.

1. 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 $5.2 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.

2. 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 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. As with the ricin vaccine, 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.

3. 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.

C. BioTherapeutics Division

1. 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.

2. 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. Based on the outcome of the data we are scheduling a meeting with the FDA to receive their guidance on the appropriate next steps for the development of orBec®.

In addition to the pivotal trial, we are 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.

3. 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 often progress. In its most severe form, iGVHD leads 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 8,000 annual allogeneic transplant patients in the United States will develop some form of acute iGVHD.

4. 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.

D. 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
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

Therapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of acute Graft-versus-Host Disease with intestinal involvement	Pivotal Phase III Clinical Trial Completed

E. Summary of Products Not Currently Being Actively Developed

The following is a brief description of products that we currently are not actively developing and that are 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 and includes 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 the products.

1. 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®. 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. The oral suspension may provide a convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

2. 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.

3. LPE™ and PLP™ Systems for 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, particularly perillyl alcohol. 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.

F. The Drug Approval Process

1. 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.

2. Marketing Strategies

We believe that we will be able to identify a marketing partner for orBec® in the U.S. and Europe. To that end we are presently seeking a marketing partner for orBec® in iGVHD and all other potential indications.

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.

3. 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.

4. 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., Antex Biologics, 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.

5. 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.

6. 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. Neither the active ingredient of orBec®, beclomethasone diproprionate, nor its use in the treatment of intestinal graft versus host disease, our initial indication, is currently protected by issued patents in the U.S. or elsewhere. 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.

7. 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®.

8. 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.

9. 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.

10. 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 requires 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, 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.

11. Employees

As of March 2, 2005, we had nine full-time employees, four of whom are Ph.D.s.

Information regarding our executive officers is set forth in Items 9 and 10 of this Annual Report, which information is incorporated herein by reference.

12. Research and Development Spending

We spent approximately $3.6 million and $2.7 million on research and development for the years ended 2004 and 2003, respectively.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933 that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are subject to significant risks, uncertainties, and other factors, including those identified in "Risk Factors" below, which may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this Form 10-KSB may be identified by words such as "believes," "anticipates," "expects," "intends," "may," "would," "will" and other similar expressions. However, these words are not the exclusive means of identifying these statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-KSB with the SEC or for any other reason. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Risk Factors

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this Annual Report, including our financial statements and the 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 December 31, 2004 we had $2.3 million in cash available. As a result of our private placement in February 2005, which brought in gross proceeds of approximately $3.77 million, we expect to have enough funds to meet our anticipated cash needs for the next 12 months. In addition, through the NIH 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 December 31, 2004, we had expended approximately $6.3 million developing our current product candidates for preclinical research and development and clinical trials, and we currently have commitments to spend at least $7.1 million over the next two years in connection with development 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.

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:

- that 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;
- that we will encounter problems in clinical trials; or
- that 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.

All of our product offerings, as well as the processes and facilities by which they are manufactured, are 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 70% reduction in mortality compared to placebo. We plan to continue discussions with the FDA to determine the next steps in the development of orBec®. 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 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 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 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 in large part 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 are aware of at least one issued U.S. patent assigned to the U.S. Government

relating to one component of one of our vaccine candidates that we may be required to license in order to commercialize that vaccine candidate. 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 nine 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. Furthermore, these few employees on whom our business depends have limited experience in managing and operating our business. 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; Dr. Gregory Davenport, the President of BioDefense Division, was hired in December 2003; 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. In addition, our President and Acting Chief Executive Officer, Geoff Green and our Controller, William Milling, resigned in the fourth quarter of 2004. 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 our Common Stock

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 stock price has fluctuated between January 1, 2001 through December 31, 2004, the per share price of our common stock ranged between a high of $2.10 per share to a low of $0.11 per share. As of March 2, 2005 our common stock traded at $0.43. 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 2004, the stockholders' equity standard applicable to us of the American Stock Exchange's (AMEX) continued listing requirements is $6 million. As of February 7, 2005 on the raising of approximately $3.77 million through a private equity placement we were in compliance with the standard. However in order to continue to be in compliance with the listing standard we must execute the compliance plan submitted on December 30, 2004 with AMEX and approved by them on January 19, 2005. Despite our current compliance, AMEX may require that we also demonstrate continued compliance with all listing requirements by July 12, 2005, including minimum stockholders' equity of at least $6 million at such time. Based upon our forecasted cash expenditures, we may not satisfy such requirement at such time absent one or more transactions having the effect of increasing our current stockholders' equity.

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. 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. However, we cannot 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 for any reason, 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.

Shareholders 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 22.4 million shares of our common stock at a current weighted average exercise price of approximately $1.04;

· 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 11.8 million shares of our common stock of a current weighted average exercise price of approximately $0.64.

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.

Item 2. 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 September 15, 2006. We believe that our current leased facilities are sufficient to meet our current and foreseeable needs.

Item 3. Legal Proceedings

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

PART II

Item 5. 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, for the period from January 1, 2003 through December 31, 2004. 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

As of March 2, 2005, the last reported price of our common stock was $0.43 per share. We have approximately 1,093 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.

Item 6. 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 "Item1. Description of Business-Risk Factors" in this Annual Report. See "Item1 .Description of Business-Cautionary Note Regarding 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 potential submission of a New Drug Application for orBec® with the U.S. Food and Drug Administration for treatment of acute Graft-versus-Host Disease with gastrointestinal involvement; (b) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (c) consider prophylactic use studies of orBec®; (d) identify a marketing and sales partner for orBec® in the U.S. and abroad; (e) secure government funding for each of our biodefense programs through grants and procurement contracts; (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; and (i) acquire or in-license new clinical-stage compounds for development.

orBec®

In order to meet our goal of submitting a New Drug Application for orBec® in 2005, we are implementing a number of strategies aimed at improving our FDA approval prospects. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the New Drug Application preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is ongoing and these batches are currently undergoing stability testing.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. It is our intent to secure a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to secure a partner for the other potential indications of orBec®.

RiVax™

The scientific development of our ricin vaccine has progressed significantly in the past year. With our partner the University of Texas Southwestern Medical Center, the initial goal was met for this program to file an Investigational New Drug application with the FDA for the purposes of conducting a Phase I clinical trial in healthy human volunteers and a Phase I safety and immunogenicity trial is currently being conducted. The current vaccine is being developed for intramuscular delivery. We are working on a formulation technology that could permit the vaccine to be delivered nasally, with the objective of providing immunity in the respiratory tract.

BT-VACC™

The botulinum vaccine program has made important strides in the last year and we have identified a lead antigen against one serotype of botulinum toxin. We are in the process of validating the data and creating a multivalent botulinum vaccine through a CRADA (Cooperative Research and Development Agreement) with the U.S. Army and Thomas Jefferson University. To date much of the work at Thomas Jefferson University has been funded by us, and we plan to continue to fund the development of additional antigens against other serotypes of botulinum toxin. In addition, we have applied for and intend to continue to apply for research grants from the U.S. government to fund the transition of the manufacturing of the lead antigen from the academic center to commercial facilities. The goal of our biodefense program is to supply the United States government with qualified countermeasures that will protect its 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. 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.

Material Changes in Results of Operations

We are a research and development company. 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 NIH grant is $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 December 31, 2004, we had cash and cash equivalents of $2,332,190 as compared to $4,117,539 as of December 31, 2003 and working capital of $1,055,922 as compared to $3,287,045 as of December 31, 2003. For the 12 months ended December 31, 2004, our cash used in operating activities was approximately $4.4 million, versus approximately $4.3 million in 2003.

In 2004, we granted options to employees and directors that were conditional upon stockholder approval of an amendment to our 1995 omnibus option plan. Therefore, a measurement date did not exist, until approval could be gained at our annual stockholder meeting. In December 2004, we recorded a noncash expense of $284,555.

In 2003, we granted options to employees and directors that were conditional upon stockholder approval of an amendment to our 1995 omnibus option plan. Therefore, a measurement date did not exist until approval could be gained at our annual stockholder meeting in April 2005. In September 2003, we recorded an expense of $954,850 as well as an expense of $50,148 for options granted to consultants.

We expect our expenditures for 2005, under existing product development agreements and license agreements pursuant to letters of intent and option agreements to approximate $2.9 million. We anticipate grant revenues to offset manufacturing and research expenditures for the development of our ricin vaccine in the amount of approximately $2.5 million, pending completion of certain milestones.

As of December 31, 2004, we had a note due of $115,948, which represents the remaining amount payable to a pharmaceutical company in connection with our joint ventures in which we were required to make payments of $231,897 in June 2004 and $115,948 in December 2004. As of the date of this Annual Report we have not made the final payment.

The following summarizes our contractual obligations at December 31, 2004, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	Year 2005	Year 2006	Year 2007

Non-cancelable obligations (1)	$	66,914	$	52,628		-
Debt (2)		115,348		-		-
TOTALS	**$**	**182,262**	**$**	**52,628**	**$**	**-**

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

(2) Debt consists of payment due to Élan as part of the dissolution of the joint ventures

In March 2004, we supplemented our cash position by the issuance and sale of 4,113,924 shares of our common stock at $0.79 per share in a private placement to institutional investors. We also issued to such investors warrants to purchase an aggregate of 1,645,570 shares of our common stock at an exercise price of $0.87 per share. Our proceeds after related expenses and closing costs, were approximately $3.0 million.

In February 2005, we further supplemented 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 an aggregate of 6,297,075 shares of our common stock at an exercise price of $0.505 per share. Our proceeds after related expenses and closing costs, were approximately $3.5 million. With this financing we believe our current cash position will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the next 12 months. However, within this period, we may decide to seek additional capital in the private and/or public equity markets to support a higher level of growth, to respond to competitive pressures, to develop new products and services and to support new strategic partnership expenditures. After that 12-month period, if cash generated from operations is insufficient to satisfy our liquidity requirements, we may need to raise additional funds through public or private financing, strategic relationships or other arrangements. If we receive additional funds through the issuance of equity securities, stockholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. Further, we may not be able to obtain additional financing when needed or on terms favorable to our stockholders or us. If we are unable to obtain additional financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities or respond to competitive pressures.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Item 7. Financial Statements.

See Item 13(1) of this Annual Report.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures

Our chief executive officer and our chief financial officer (the "Certifying Officers") are responsible for establishing and maintaining disclosure controls and procedures. Such officers have concluded (based upon their evaluations of these controls and procedures as of the end of the period covered by this report) that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in this report is accumulated and communicated to management, including the Certifying Officers as appropriate, to allow timely decisions regarding required disclosure.

The Certifying Officers have also indicated that there were no significant changes in our internal controls over financial reporting or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no significant deficiencies and material weaknesses.

Our management, including the Certifying Officers, does not expect that our disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any systems of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of these inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Item 8B. Other Information

None.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

The following table contains information regarding the current members of the 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.	41	Vice Chairman
Michael T. Sember, M.B.A.	55	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	40	Chief Financial Officer, and Director
James S. Kuo, M.D., M.B.A.	40	Director
Stuart D. Sedlack, M.B.A.	40	Director
Gregory Davenport, Ph.D.	36	President, BioDefense
Robert N. Brey, Ph.D.	54	Chief Scientific Officer
James Clavijo, C.P.A., M.A.	39	Controller, Treasurer, and Corporate Secretary

Alexander P. Haig, J.D., *Chairman of the Board*

Mr. Haig 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., *Vice Chairman of the Board*

Mr. Kanzer has served as a member of our board of directors 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 Solovax, Inc., Effective Pharmaceuticals, Inc., CD4 Biosciences, Inc., Pipex, Inc. and Experimental Therapeutics, Inc., each of which are involved in the licensing and development of clinical stage investigational new drugs for a variety of diseases. 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. 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.

Michael T. Sember, M.B.A., *Chief Executive Officer, President and Director*

Mr. Sember became our 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 Elan 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. Mr. Sember received a bachelor’s degree from the University of Pittsburgh and a Master of Business Administration degree from Rockhurst University.

Evan Myrianthopoulos, *Chief Financial Officer and Director*

Mr. 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.

James S. Kuo, M.D., M.B.A., *Director*

Dr. Kuo has been a director since 2004. Dr. Kuo is a founder, Chairman and Chief Executive Officer of BioMicro Systems, since January 2003, a private nanotechnology company. Formerly, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories, 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. Prior to that, he served as Vice President Worldwide Business Development, from 2000 to 2001, 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 board 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.

Stuart Sedlack, *Director*

Mr. Sedlack has been a director since 2004. Since April 2004, Mr. Sedlack is Head of Negotiations, Global Business Development Business Franchise, Infectious Diseases at Novartis Pharma AG. Prior to that, Mr. Sedlack was with Élan Corporation, PLC, from May 1997 to September 2003, as Corporate Vice President, Business Development, where he was responsible for strategic licensing, new investments, portfolio management activities, and restructurings. Prior to joining Élan, he served as Director for the Office of Technology Development for the University of Maryland Medical System in Baltimore, MD. Mr. Sedlack began his career in banking and finance working for MNC International Bank and ABN AMRO Bank, N.V. Mr. Sedlack has served on the Board of Directors of several healthcare companies including Ardent Pharmaceuticals, Targeted Molecules Corporation, Digital Gene Technologies, and Celtrix Pharmaceuticals. After receiving a bachelor's degree in economics from the University of Richmond, Mr. Sedlack went on to receive a Master of Business Administration degree from Babson College .

Gregory Davenport, Ph.D., *President Bio Defense Division*

Dr. Davenport, joined our company in December 2003, as Vice President for Business Development and was recently promoted to President, BioDefense Division. In such capacity, Greg will now oversee and manage the activities of our Biodefense Division that is developing biomedical countermeasures to help address the threat of bioterrorism. Dr. Davenport brings over 10 years of experience in the biotechnology sector. Prior to joining he was Director of Vaccine Technology / Business Development, from June 2001 to December 2003, for Dynport Vaccine Company. He was responsible for technical evaluations and assessments of novel technologies, particularly in the area of vaccine delivery systems and production methods, and establishing strategic relationships and research collaborations as well as pursuing federal funding, which resulted in several new funded initiatives. Before that, Dr. Davenport received an undergraduate degree in Biology from Dillard University in New Orleans, Louisiana, his Ph.D. in Molecular Biology from Howard University in Washington, D.C., and performed postdoctoral studies at the University of Maryland Medical Center and George Washington University Medical Center, from September 1998 to May 2001, where he worked on a number of therapeutic targets, including sickle cell anemia, leukemia, and breast cancer.

Robert N. Brey, Ph.D., *Chief Scientific Officer*

Since 1996, Dr. Brey has held various positions within our company, including Vice President, Vaccine Development and Vice President, Research and Development, as well as principal vaccine consultant. He also has held scientific, management and project management positions in the Lederle-Praxis division of American Cyanamid, now a division of Wyeth, which developed a pediatric conjugate vaccine for Haemophilius influenzae meningitis, and a conjugate vaccine for pneumonia, both now recommended for routine pediatric immunization and commanding market dominance. While at Lederle-Praxis, Dr. Brey managed Molecular Biology research for vaccines and was project manager for development of oral vaccines from 1985 through 1993. He has been instrumental in the development of the Haemophilus conjugate and pediatric combination vaccines. From 1993 through 1994, Dr. Brey served as Director of Research and Development of Vaxcel, a company formed to exploit adjuvant technology and formulations for

improved vaccines. From 1994 through 1996, Dr. Brey established an independent consulting group, Vaccine Design Group, to identify and develop novel vaccine technologies and platforms. From 1996 through 2000, in addition to serving as our Vice President, he served as Corporate Vice President of InnoVaccines Corporation, our joint venture with Elan Pharmaceutical Technologies. Before entering into drug and vaccine delivery, from 1982 through 1986 he held senior scientific positions at Genex Corporation, one of the first biotechnology companies formed to exploit genetic engineering. Dr. Brey received an undergraduate degree in biology from Trinity College in Hartford, Connecticut, his Ph.D. in microbiology from the University of Virginia and performed postdoctoral studies at MIT with Nobel laureate Salvador Luria. Dr. Brey is an inventor or co-inventor of 10 U.S. patents in the area of vaccines. He is a permanent member of NIH Vaccines against Microbial Diseases review committee and serves as an editor of Advanced Drug Delivery Reviews.

James Clavijo, C.P.A., M.A., *Controller, Treasurer, and Corporate Secretary*

Mr. Clavijo joined our company in October 2004. 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.

General Alexander M. Haig, Jr., *Strategic Advisory Board*

Mr. Haig currently serves on our Strategic Advisory Board. He previously served as Chairman of the Board of Directors from December 2002 to November 2004. Since 1984, Mr. Haig has been Chairman and President of Worldwide Associates, Inc., a Washington D.C. based international advisory firm. He served as Secretary of State (1981-82), President and Chief Operating officer of United Technologies Corporation (1979-81), and Supreme Allied Commander in Europe (1974-79). Previously, he was White House Chief of Staff for the Nixon and Ford administrations, Vice Chief of Staff of the U.S. Army and Deputy National Security Advisor. Mr. Haig currently serves on the Board of Directors of MGM Mirage, Inc. and Metro-Goldwyn Mayer, Inc. He is also the host of his own weekly television program, "World Business Review".

Section 16(a) Beneficial Ownership Reporting Compliance

We are required to identify each person who was an officer, director or beneficial owner of more than 10% of our registered equity securities during our most recent fiscal year and who failed to file on a timely basis reports required by Section 16(a) of the Securities Exchange Act of 1934.

To our knowledge, based solely on our review of the copies of such reports received by us, and representations from certain reporting persons, we believe that, during the year ended December 31, 2004, our directors, executive officers and significant stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act, except

Form 4's for Evan Myrianthopoulos (two filings); Peter Salomon (two filings); Larry Kessel (two filings); and Arthur Kornbluth (one filing).

Code of Ethics

We have adopted a code of ethics that applies to all of our executive officers and senior financial officers (including our chief executive officer, chief financial officer, chief accounting officer, controller, and any person performing similar functions). A copy of our code of ethics is publicly available on our website at http://www.dorbiopharma.com under the caption "Investors." If we make any substantive amendments to our code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our chief executive officer, chief financial officer, chief accounting officer or controller, we will disclose the nature of such amendment or waiver in a report on Form 8-K.

Audit Committee Financial Expert

We have an audit committee comprised of Dr. Kuo and Mr. Sedlack. The board of directors has determined that Dr. Kuo qualifies as an "audit committee financial expert," as defined under the rules of the Securities and Exchange Commission. The board of directors has also determined that all of the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee.

Item 10. Executive Compensation.

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2002, 2003 and 2004, to the persons who served as our Chief Executive Officers, and each of the four other most highly compensated executive officers during 2004 (collectively, the "Named Executive Officers").

Name	Position	Years	Annual Salary	Annual Bonus	Long term Compensation Awards Securities Underlying Options
Michael Sember (1)	CEO	2004	$20,000	-	2,000,000
Evan Myrianthopoulos (2)	CFO	2004	$25,694	-	650,000
Gregory Davenport, Ph.D. (3)	President	2004	$124,375	$25,000	600,000
	BioDefense	2003	$9,583	-	-
Robert Brey, Ph.D. (4)	CSO	2004	$155,000	-	-
		2003	$164,637	-	-
		2002	$254,000	-	-
James Clavijo (5)	Controller	2004	$27,500	-	100,000
Geoff Green (6)	Acting	2004	$124,490	$26,667	700,000
	CEO	2003	$55,464	-	-
Ralph Ellison (7)	CEO	2004	$323,076	$108,333	2,000,000
		2003	$200,000	-	-

(1) Mr. Sember joined in December 2004.

(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.

(3) Dr. Davenport joined in December 2003.

(4) Dr. Brey joined in December 1996.

(5) Mr. Clavijo joined in October 2004.

(6) Mr. Green joined in July 2003 as Vice President, Clinical Operations and then in July 2004 accepted the position of President and Acting Chief Executive Officer. Mr. Green resigned in November 2004.

(7) Dr. Ellison joined in March 2003 and resigned in July 2004.

The following table contains information concerning options granted to the Named Executive Officers during the fiscal year ended December 31, 2004. We have never issued Stock Appreciation Rights.

Option Grants in Last Fiscal Year

Named Executive Officer	Number of Securities Underlying Options Granted (1)(2)	Percentage of Total Options Granted to Employees in Fiscal Year (3)	Exercise Price ($/share)	Expiration Date
Michael Sember (4)	2,000,000	44 %	$0.46	12/7/2014
Evan Myrianthopoulos (5)	650,000	14 %	$0.47-$0.49	12/9/2014 & 11/10/2014
James Clavijo (6)	100,000	2 %	$0.47	10/22/2014
Gregory Davenport (7)	100,000	2 %	$0.55	9/29/2014

(1) Dr. Brey, Dr. Ellison and Mr. Green did not receive any options during fiscal year 2004.

(2) Based on options to purchase an aggregate of 4,500,000 shares of our common stock granted to employees and non-employee board members in the fiscal year ended December 31, 2004, including all options granted to the Named Executive Officers in all capacities in the fiscal year ended December 31, 2004.

(3) 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.

(4) Mr. Sember's options vested 680,000 on date of grant, December 7, 2004, with the balance vesting every three months from grant date, at a rate of 110,000 options per three month period.

(5) Mr. Myrianthopoulos has 500,000 options that will vest quarterly on each three month anniversary of December 9, 2004 at 41,667 per period and he has 150,000 options which vested immediately on November 10, 2004. The exercise price on these options was $ 0.49 and $0.47, respectively.

(6) Mr. Clavijo's options vested 33,333 after one year of service, 33,333 after second year of service and 33,334 after the third year of service.

(7) Dr. Davenport's options vested immediately upon meeting milestones.

Fiscal Year-End Option Table

The following table provides information on the total number of exercisable and unexercisable stock options held at December 31, 2004 by the Named Executive Officers. None of the Named Executive Officers exercised any options during fiscal year 2004.

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	
Named Executive Officer	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable(1)**
Michael Sember	680,000	1,320,000	-	-
Evan Myrianthopoulos	150,000	500,000	-	-
James Clavijo	-	100,000	-	-
Gregory Davenport	150,000	450,000	-	-
Rob Brey	115,000	-	-	-
Ralph Ellison	2,000,000	-	-	-
Geoff Green	200,000	-	-	-

(1) Based on the difference between the option's exercise price and a closing price of $0.64 for the underlying common stock on December 31, 2004 as reported by the American Stock Exchange.

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 shareholder approval. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Clavijo three months severance, as well as any unpaid bonuses and accrued vacation would become payable. 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 shareholder approval. 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 would become payable. 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 shareholder approval. 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 would become payable. No unvested options shall vest beyond the termination date.

During September 2004, we entered into a one year employment agreement with Gregory Davenport, Ph.D. Pursuant to this employment agreement we agreed to pay Dr. Davenport a base salary of $140,000 per year. After one year of service Dr. Davenport would be entitled to a minimum annual bonus of 20% of his annual salary. We agreed to issue him options to purchase 600,000 shares of our common stock, with options vesting based on milestones. Upon termination without "just cause" as defined by this agreement, we would pay Dr. Davenport three months severance, as well as any unpaid bonuses and accrued vacation would become payable. All options would become fully vested and he would have 90 days to exercise those options.

During July 2003, we entered into a three year employment agreement with Geoff Green. Pursuant to this employment agreement we agreed to pay Mr. Green a base salary of $100,000 per year. After one year of service he would be entitled to an annual bonus of $20,000. We agreed to issue him options to purchase 300,000 shares of our common stock, with one third immediately vesting and the remainder vesting over two years. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Green three months severance, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. In November 2003, Mr. Green also received options to purchase 400,000 shares of our common stock, with vesting based on milestones. In July 2004, Mr. Green accepted the position of President and Acting Chief Executive Officer and received an increase in salary to $145,000. On November 9, 2004, Mr. Green resigned.

During March 2003, we entered into a three year employment agreement with Ralph M. Ellison M.D., M.B.A. Pursuant to this employment agreement we agreed to pay Dr. Ellison a base salary of $200,000 per year. Upon the completion of the equity financing, Dr. Ellison received an increase in base salary to $300,000 per year, as well as a bonus on his anniversary of 30% of his yearly salary. 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 two years. Upon termination without "just cause" as defined by this agreement, we would pay Dr. Ellison six months severance, as well as any unpaid bonuses and all of his options would immediately become vested in full. On July 9, 2004, Dr. Ellison resigned from the Company and entered into a separation agreement and general release in which we agreed to pay Dr. Ellison six months’ severance and provide him with the right to exercise his 2,000,000 vested options received pursuant to his employment agreement for a period of one year from his resignation 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 General Haig is its President.

On December 23, 2002, we entered into a letter agreement with 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, the retainer portion of this agreement was terminated and General Haig was given three years in which to exercise his options.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The table below provides information regarding the beneficial ownership of the Common Stock as of March 2, 2005. 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 50,612,504 shares of common stock outstanding.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
SF Capital Partners (1)	6,494,705	12.19 %
Silverback (2)	3,885,000	7.43 %
Alex P. Haig (3)	500,000	0.98 %
Steve H. Kanzer (4)	2,085,635	4.02 %
Michael T. Sember (5)	790,000	1.54 %
Evan Myrianthopoulos (6)	628,009	1.23 %
James Kuo (7)	100,000	*
Stuart Sedlack (8)	100,000	*
James Clavijo (9)	50,000	*
Greg Davenport (10)	150,000	*
Robert Brey (11)	115,000	*
Ralph Ellison (12)	2,000,000	3.80 %
Geoff Green (13)	-	*
All directors and executive officers as a group (7 persons)	4,253,644	8.25 %

* Indicates less than 1%.

(1) Includes the 3,817,046 of common stock shares 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 13 G filed with the SEC on February 9, 2005. The address for SF Capital Partners Ltd. is 3600 South Lake Drive St. Francis, WI 53235.

(2) Includes the 2,220,000 of common stock shares beneficially owned by Silverback Master Ltd. and Silverback Life Sciences Master Fund, and 1,665,000 shares of common stock issuable upon exercise of warrants until August 2010. Reference to this was as reported on Schedule 13 G filed with the SEC on February 2, 2005. The address for Silverback is 1414 Raleigh Road, Suite 250, Chapel Hill, NC 27517.

(3) Includes 500,000 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Haig is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(4) Includes 819,437 shares of common stock owned by Mr. Kanzer and 349,398 warrants to purchase shares of common stock and 916,800 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Kanzer is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(5) Includes 790,000 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Sember is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(6) Includes 628,009 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(7) Includes 100,000 options to purchase common stock and 5,000 warrants to purchase shares of common stock within 60 days of March 2, 2005. The address of Dr. Kuo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(8) Includes 100,000 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Sedlack is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(9) Includes 50,000 options to purchase common stock within 60 days of March 2, 2005. The address of Mr. Clavijo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(10) Includes 150,000 options to purchase common stock within 60 days of March 2, 2005. The address of Dr. Davenport is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(11) Includes 115,000 options to purchase common stock within 60 days of March 2, 2005. The address of Dr. Brey is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(12) Includes 2,000,000 options to purchase common stock within 60 days of March 2, 2005. The address of Dr. Ellison is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(13) Mr. Green's options had expired as of March 2, 2005. The address of Mr. Green is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under our equity compensation plans as of December 31, 2004:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-Average Exercise Price Outstanding options, warrants and rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders (1)	10,000,000	$ 0.66	-
Equity compensation plans not approved by security holders (2)	1,764,339	$ 0.47	-
TOTAL	**11,764,339**	**$ 0.64**	**-**

(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan (the "Plan").

(2) The excess options awarded will be subject to shareholder approval to increase the number of options available under the Plan at our 2005 Annual Meeting of stockholders.

Item 12. Certain Relationships and Related 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 approximately $0.8756 per share.

In connection with our 2003 private placement, Paramount Capital, Inc., an investment bank associated 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 March 2003, we issued 150,000 options each to Peter Salomon and Larry Kessel, members of our Board of Directors, as a finder’s fee in connection with the hiring of Ralph Ellison, M.D. as our CEO and President.

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.

Item 13. Exhibits

The following financial statements and exhibits are filed as part of this Annual Report:

(1) Financial Statements:

(i) Report of Independent Registered Public Accounting Firm.

(ii) Consolidated Balance Sheets as of December 31, 2004 and December 31, 2003.

(iii) Consolidated Statement of Operations for the years ended December 31, 2004 and 2003.

(iv) Consolidated Statement of Cash Flows for the years ended December 31, 2004 and 2003.

(v) Consolidated Statement of Stockholders' Equity for the years December 31, 2004 and 2003.

(vi) Notes to Consolidated Financial Statements.

(2) Exhibits:

3.1 Amended and Restated Certificate of Incorporation. (10)

3.2 By-laws. (11)

4.1 Form of Investor Warrant issued to each investor dated as of April 12, 2000. (1)

4.2 Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000. (1)

4.3 Warrant issued to Aries Fund dated as of May 19, 1997. (1)

4.4 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997. (1)

4.5 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997. (2)

4.6 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997. (2)

4.7 Warrant issued to Élan International Services, Ltd. dated January 21, 1998. (3)

4.8 Form of Warrant to be issued to CTD warrant holders. (4)

4.9 Form of Warrant issued to each investor in the December 2002 private placement.

4.10 Form of Warrant issued to each investor in the September 2003 private placement. (8)

4.11 Form of Warrant issued to each investor in the March 2004 private placement. (9)

4.12 Form of Warrant issued to each investor in the February 2005 private placement. (13)

4.13 Form of Warrant issued to Mid South Cpaital, Inc. in the February 2005 private placement. Filed Herewith.

10.1 Amended and Restated 1995 Omnibus Incentive Plan. (10)

10.2 Lease dated September 1, 2003 between the Company and L.N.R. Jefferson LLC.

10.3 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD. (5)

10.4 Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001. (7)

10.5 Termination of the Endorex Newco joint venture between the Company, Élan Corporation, Élan international services, and Elan Pharmaceutical
dated December 12, 2002. (7)

10.6 Option Agreement with General Alexander M. Haig Jr. (7)

10.7 Separation Agreement and General Release between the Company and Ralph Ellison dated July 9, 2004.

10.8 License Agreement between the Company and The University of Texas Southwestern Medical Center

10.9 License Agreement between the Company and Thomas Jefferson University

10.10 License Agreement between the Company and The University of Texas Medical Branch

10.11 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University

10.12 Form of Subscription Agreement between the Company and each investor dated July 18, 2003. (8)

10.13 Form of Securities Purchase Agreement between the Company and each investor dated March 4, 2004. (9)

10.14 Form of Registration Rights Agreement between the Company and each Investor dated March 4, 2004. (9)

10.15 Employment agreement between the Company and Greg Davenport dated September 1, 2004. Filed Herewith.

10.16 Employment agreement between the Company and Mike Sember dated December 7, 2004. Filed Herewith.

10.17 Employment agreement between the Company and Evan Myrianthopoulos dated December 9, 2004. Filed Herewith.

10.18 Employment agreement between the Company and James Clavijo dated February 18, 2005. Filed Herewith.

10.19 Form of Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (13).

10.20 Amendment No. 1 dated February 17, 2005 to the Securities Purchase Agreement between the Company and each investor dated February 1, 2005. Filed Herewith.

10.21 Form Registration Rights agreement between the Company and each investor dated February 1, 2005 (13).

21.1 Subsidiaries of the Company. Filed Herewith.

31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002. Filed Herewith.

31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002. Filed Herewith.

32.1 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002. Filed Herewith.

32.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002. Filed Herewith.

* Management contract or compensatory plan or arrangement.

(1) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000.

(2) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997.

(3) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997.

(4) Incorporated by reference to our Registration Statement on Form S-4 filed on October 2, 2001.

(5) Incorporated by reference to our current report on Form 8-K filed on December 14, 2001.

(6) Incorporated by reference to our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2001.

(7) Incorporated by reference to our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002.

(8) Incorporated by reference to our current report on Form 8-K filed on July 18, 2003.

(9) Incorporated by reference to our current report on Form 8-K filed on March 4, 2004.

(10) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003.

(11) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003.

(12) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2003.

(13) Incorporated by reference to our current report on Form 8-K filed on February 3, 2005.

Item 14. Principal Accountant Fees and Services

		December 31, 2004		2003
Audit fees	**$**	**65,574**	$	173,895
Audit related fees		**-**		15,795
Tax fees		**22,488**		20,447
Total	**$**	**88,062**	$	210,137

Audit Fees

The aggregate fees billed during the years ended December 31, 2004 and 2003 by Sweeney, Gates & Co., our principal accountants in 2004 and 2003, for the audit of our financial statements for each of those years and the review of our financial statements included in our Quarterly Reports on Form 10-QSB during those financial years were $65,574 and $41,975, respectively. Our former principal accountants, Ernst & Young LLC, were paid $151,920 for the 2003 audit of our financial statements and the review of our financial statements included in our Quarterly Reports on Form 10-QSB.

Audit Related Fees

Neither of our principal accountants billed us any fees during the years ended December 31, 2004 and 2003 for any assurance and related services.

Tax Fees

Our current principal accountants Sweeney, Gates & Co. billed us $22,488 for tax compliance, tax advice and tax planning for the year ended December 31, 2004.

Other Fees

Neither of our principal accountants billed us for any services or products other than as reported above in this Item 14 during our fiscal years ended December 31, 2004 and 2003.

Pre Approval Policies and Procedures

The audit committee has adopted a policy that requires advance approval of all audit services and permitted non-audit services to be provided by the independent auditor as required by the Exchange Act. The audit committee must approve the permitted service before the independent auditor is engaged to perform it.

The audit committee approved all of the services described above in accordance with its pre-approval policies and procedures.

DOR BIOPHARMA, Inc. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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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.

Fort Lauderdale, Florida
February 16, 2005

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

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

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	Treasury
	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	-	-
	)	)	2,886,438	2,886	-	-	12,817,417	-	-

Conversion of preferred stock to common stock	(128,203	(12,820,303							
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

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**		1,070,025
Net cash used by operating activities		**(4,407,776)**		(4,218,506)
Investing activities:				
Intangible assets		**(267,096)**		(319,505)
Purchases of equipment		**(10,559)**		(17,854)
Proceeds from assets sold or retired		**-**		103,407
Net cash used by investing activities		**(277,655)**		(353,292)
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

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.

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.

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.

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

	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)**	1,630,587

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**

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:

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

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.

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

	Lease Payments
2005	$ 66,914
2006	52,628

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	**$ (6,248,776)**	$ (5,226,881)
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

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DOR BIOPHARMA, INC.

By: /s/Michael T. Sember
Michael T. Sember, Chief Executive Officer and President

Date: March 11, 2005

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated, on March 11, 2005.

Signature	**Title**
/s/ Alexander P. Haig Alexander P. Haig	Chairman of the Board
/s/ Michael T. Sember Michael T. Sember	Chief Executive Officer, President and Director (Principal Executive Officer)
/s/ Steve H. Kanzer Steve H. Kanzer	Vice-Chairman of the Board
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Chief Financial Officer and Director (Principal Financial Officer)
/s/ James Clavijo James Clavijo	Controller, Treasurer, and Corporate Secretary (Principal Accounting Officer)
/s/ James S. Kuo James S. Kuo	Director
/s/ Stuart Sedlack Stuart Sedlack	Director