DOR BIOPHARMA INC
Form 10KSB
March 30, 2004

As filed with the Securities and Exchange Commission on March 30, 2004

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, 2003
OR
[__] TRANSITION REPORT UNDER 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 (State or other jurisdiction of incorporation or organization)	41-1505029 (I.R.S. Employer Identification Number)

1691 Michigan Ave, Suite 435 Miami, FL 33139 305-534-3383

(Address, including zip code, and telephone number, including area code of registrant s principal executive offices)

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 Securities Exchange act:

Title of Each Class of Securities to be Registered	Name of Each Exchange on Which Registered
None	None

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the 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 : $83,817
The aggregate market value of the common stock held by non-affiliates (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), computed by reference to the closing price of such stock as of March 24, 2004, was $34,854,985.
At March 24, 2004, 42,032,936 shares of the registrant s common stock (par value $.001 per share) were outstanding.
Transitional Small Business Issuer: Yes [_] No [X]
Documents Incorporated by Reference

PART I

Item 1. Description of Business.

This report 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 Form 10-KSB. See "Cautionary Note Regarding Forward Looking Statements."

Overview

Company Overview

We are a biopharmaceutical company focused on the development of biodefense vaccines and therapeutics for unmet medical needs. Through our biodefense division, we are developing bioengineered vaccines designed to protect against the deadly effects of exposure to ricin and botulinum toxins, both of which are considered serious bioterrorism threats. The technologies, which were exclusively licensed by us from two leading university research centers, are currently undergoing efficacy and toxicity testing in animals prior to initiating human clinical trials. Through our therapeutics division, we are developing orBec ® (oral beclomethasone dipropionate) for the treatment of intestinal inflammation associated with acute Graft-versus-Host Disease (GvHD), a condition that affects a large percentage of allogeneic bone marrow transplant patients. OrBec® is an orally-delivered, potent, locally acting corticosteroid that reduces inflammation within the tissue of the gastrointestinal tract. There is currently no Food and Drug Administration (FDA) approved products for the treatment of acute intestinal GvHD. OrBec® is being tested in a pivotal phase III clinical trial with the goal of filing a New Drug Application (NDA) with the FDA in late 2004. We are also considering oral beclomethasone dipropionate for a number of additional therapeutic indications that involve inflammatory conditions of the gastrointestinal tract. Our business strategy is to (a) build value in our existing product candidates by efficiently advancing their development with assistance from government grants and corporate partners, and (b) grow our product portfolio through the strategic acquisition and/or in-licensing of additional clinical stage product opportunities.

Biodefense Program

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 produced in bacterial hosts and both consist of non-toxic subunits of the native toxins. These subunits retain the ability to induce antibodies that completely neutralize the toxins from which they are derived. We have secured the intellectual property rights for each of these vaccines.

Ricin 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 and water contaminant. The U.S. Centers for Disease Control and Prevention 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. O nce exposed to ricin toxin, there is no effective therapy 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 the use of ricin as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

The development of our vaccine for ricin intoxication stems from the research (Smallshaw et al., 2002 Vaccine) of Dr. Ellen Vitetta at the University of Texas Southwestern Medical Center in Dallas, Texas. This research has shown that a modified subunit of ricin toxin is non-toxic and highly immunogenic in animals. The vaccine has induced protective immunity in 100% of treated mice challenged with natural 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. Firstly, 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, we believe that 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 protecting animals against exposure to lethal doses of ricin toxin (Smallshaw et al., 2002 Vaccine) . In collaboration with UT Southwestern, we are conducting further tests of the vaccine for toxicity and efficacy which should provide the basis for conducting human clinical trials. 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 UT Southwestern for its ricin antigen.

Botulinum Vaccine

Botulinum toxin is the product of the ubiquitous bacteria Clostridium botulinum . C. botulinum is found in soil and marine sediments; the spores can be detected on fruits and vegetables and in seafood. The bacterium produces the neurotoxin botulinum toxin, the most poisonous natural substance known to mankind. Botulinum toxin causes acute, symmetric, descending paralysis that would typically present 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 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 likely require multiple antigens (trivalent or pentavalent) to protect against the different serotypes. Currently 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. The antigen consists of a modified segment of the heavy chain of botulinum toxin that is non-toxic and immunogenic after either oral or intranasal administration. The antigen elicits antibodies that protected 100% of vaccinated animals against 30,000 times the lethal dose of native toxin. We are currently validating the safety and efficacy data in further animal studies. As with the ricin vaccine, our goal is to produce a multivalent vaccine and have it available for the U.S. government s Strategic National Stockpile. We have an exclusive license agreement with Thomas Jefferson Universtiy for the oral and intranasal use of a botulinum toxin vaccine.

BioTherapeutic Program

orBec ®

Our lead 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® is currently being tested in a

multicenter, placebo-controlled phase III clinical trial to treat acute Graft-versus-Host Disease (GvHD) with gastrointestinal involvement. Acute intestinal GvHD 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. A variety of additional diseases for which a potent, topically-active oral corticosteroid could be beneficial include 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 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 GvHD with intestinal involvement. The two-pill combination is comprised of an immediate-release pill designed to primarily dissolve in the stomach and proximal intestine and an enterically-coated pill designed to dissolve in the more alkaline pH portion of the small intestine.

Phase III Clinical Trial

Phase II data demonstrated that the two-pill combination of oral BDP was effective in treating intestinal GvHD, 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 is 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 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 GvHD . The target enrollment is 130 patients. The pivotal trial is currently being conducted at nineteen bone marrow transplant centers in the United States, and the product has been assigned "orphan drug" designation and "fast track" status by the FDA. The trial is a randomized, double-blind, placebo controlled safety, efficacy and pharmacokinetic trial that will serve as the basis for a New Drug Application to be filed with the FDA, assuming positive data. Our goal is to submit the New Drug Application to the FDA by the end of 2004 for an approval decision in 2005.

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 intestinal GvHD. 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 intestinal GvHD.

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 intestinal GvHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of intestinal GvHD persist and often progress. In its most severe form, GvHD 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 7,000 annual allogeneic transplant patients in the United States will develop some form of acute GvHD, with approximately 30% of those patients having intestinal involvement.

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 GvHD following hematopoietic cell transplantation, as well as Host-versus Graft Disease, as occurs following organ allograft transplantation. In addition, we are exploring the possibility of testing orBec ® for local inflammation associated with Ulcerative Colitis, Crohn s Disease, Lymphocytic Colitis, Irritable Bowel Syndrome and liver disease, among other indications.

Summary of Our Products in Development

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

Biodefense Products

Select Agent	Currently Available Countermeasure	DOR Biodefense Vaccine
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricin Vaccine
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

Therapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec Ò	Treatment of acute Graft-versus-Host Disease with intestinal involvement	Phase III

Summary of Products Not Currently Being Developed

The following is a brief description of products that we currently are not developing and that are available for licensing or acquisition.

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 an convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

LPM™ Leuprolide

LPM™ Leuprolide is an oral dosage formulation of the peptide drug, leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, by utilizing a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM Ô system incorporates biocompatible lipids and polymers and it 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 drugs/peptides. Using a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

LPE™ and PLP™ Systems for 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.

The Drug Approval Process

General

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

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

An Investigational New Drug Application is required before human clinical use in the United States of a new drug compound or biological product can commence. The Investigational New Drug Application 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 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 a new drug application 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, or at all. The FDA may deny a New Drug Application, 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.

Marketing Strategies

We believe that we will be able to identify a marketing partner for orBec ® in the U.S. and Europe. Although GvHD is a smaller indication the additional gastrointestinal disorders for which clinical trials are being considered represent larger and more attractive markets.

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

Competition

Our competitors are not only major pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we currently have, but also other biotechnology and biopharmaceutical companies. Another source of competing technologies is universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, and we face competition from other companies to acquire rights to those technologies.

Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the US Army, some of whom may have their own proprietary technologies which may directly compete with the Company s technologies. Avant Immunotherapeutics, Inc., Bioport Corporation, VaxGen, Inc., Chimerix, Inc., ID Biomedical Corporation, Human Genome Sciences, 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. For example, Avant Immunotherapeutics, Inc. has announced that they have received an $8 million contract to develop an oral plague and oral anthrax vaccines. Vaxgen and Avecia Biotechnology, Inc. have both received NIH contracts to develop a next generation injectable 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 funding. Additionally, we face competition from other companies which have existing governmental relationships, such as Dynport Vaccine Company, LLC, a prime contractor to the U.S. Department of Defense. Dynport currently has a $300 million contract to develop vaccines for the U.S. Military, including anthrax, and botulinum toxin vaccines.

orBec® Competition

Competition is intense in the gastroenterology and transplant areas being addressed by our company. Companies are attempting to develop technologies to treat graft-vs.-host disease by suppressing, through various mechanisms, the immune system. 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, Norvartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin, for transplant related therapeutics.

Competition is also intense in the therapeutic area of irritable bowel syndrome and Crohn s 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 â 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 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 diproprionate, 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 believe that the low dosage tablet , combined with the unique release characteristics of the formulation and low systemic side effects, should make orBec ® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract and other pan-intestinal diseases.

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 know-how 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. Orphan Drug status provides for 7 seven years of post approval marketing exclusivity in the US and 10 years exclusivity in Europe for orBec® use in the treatment of intestinal graft-vs.-host disease. We also have "Orphan Drug" designation in the U.S. for the prevention of graft-vs.-host-disease.

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

orBec® License Agreement

In October 1998, our subsidiary, Enteron Pharmaceuticals, Inc., 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 ® . 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®. In addition, Dr. McDonald receives $40,000 per annum as a consultant to us.

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 musocal 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 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 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. The amended license

agreement provides an option for future licensing of the microencapsulation technology.

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. We have until June 2004 to enter into the license agreement for a fee of $100,000. In June 2003, we entered into a license agreement with UT Southwestern for the injectable rights to the ricin vaccine for $200,000 of our common stock; we will also pay $100,000 in cash in June 2004 and $100,000 in cash in December 2004.

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 research support payable quarterly. 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, which Dr. Simpson received options to purchase 100,000 shares of our common stock, vesting over three years.

Employees

As of March 1, 2004, we had nine employees, eight of whom were full-time employees.

RESEARCH AND DEVELOPMENT SPENDING

We spent approximately $2.7 million and $2.9 million on research for the years ended 2003 and 2002, respectively.

Cautionary Note Regarding Forward-Looking Statements

This 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 because they 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 on Form 10-KSB, including our financial statements and the related notes.

Risks Related To Our Business and 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 development stage 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. 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 February 29, 2004, we had expended approximately $3.2 million developing our current product candidates for our clinical trials, and we currently have commitments to spend approximately $1.9 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 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 by our issuing 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 testing, 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 orBec® or any of our other product candidates:

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

· 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 orBec® or 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 subject 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. Clinical trials of our lead product candidate orBec® began in 2001 and are expected to continue for at least six more months. We do not expect to complete clinical testing of any of our product candidates within the next six months.

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.

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 our 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. We have also entered into a letter of intent with the University of Texas Southwestern Medical Center, under which we plan to license issued patent and pending patent applications for technologies relating to nasal delivery of ricin vaccine. Although this letter of intent provides for defined business terms, we may not be able to come to definitive agreements with the institutions and, as a result, may not obtain critical intellectual property rights on which we expect to rely.

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 with outside researches, 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. Virtually all 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. For example, we currently are an exclusive licensee of an issued patent in the field of use of nasally administered ricin vaccines. 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 those vaccine candidates. 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: Dr. Ralph Ellison, our Chief Executive Officer and President; Geoff Green, our Chief Operating Officer; Dr. Robert Brey our Chief Scientific Officer; Dr. Gregory Davenport, our Vice President of Business Development; William Milling, our Controller, Treasurer and Corporate Secretary; Lucy Van Pelt, our Clinical Project Manager; a Research Scientist; and an Administrative Assistant. We depend upon these nine 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. Dr. Ellison was hired in March 2003; Mr. Green was hired in July 2003; Dr. Davenport was hired in December 2003; Mr. Milling was hired in September 2002; and Dr. Brey was hired in December 2002. In addition, Alexander Haig, our Chairman of the Board, was appointed in January 2003. 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. Some of our board members are associated with other companies in the field of biopharmaceuticals and investors should not expect any obligation on the part of these directors to present opportunities to our company.

Our stock price is highly volatile.

The market price of our common stock, like that of many other development stage 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, which include, actual or anticipated fluctuations in our results of operations, announcements of innovations by us or our competitors, additions or departures of key personnel or general market conditions. For example, when ricin was discovered in an apartment in London and we announced that we had retained Mr. Haig as our Chairman of the Board on January 7, 2003; our stock price went from $0.58 per share to $1.05 per share in one day and has fluctuated between $0.63 per share and $1.57 per share from that date through March 15, 2004. From July 1, 2000 through March 15, 2004, the per share price of our common stock ranged from a high of $9.44 per share to a low of $0.11 per share, including a high of $2.10 per share and low of $0.11 per share since the beginning of 2002. 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 continuing operations in fiscal 2003, the stockholders equity standard applicable to us of the American Stock Exchange s continued listing requirements increased to $6 million for fiscal years ending 2003 and beyond. Moreover, our net equity of $2.3 million as of June 30, 2003 did not satisfy the $4 million minimum stockholders equity requirement 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 has accepted our plan and given us 18 months to regain compliance in accordance with the terms of our plan. If, however, we do not conform to our plan, or if after the 18 month period we are not in compliance with the minimum listing requirements, we may be delisted from the AMEX. Furthermore, 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.

Stockholders may suffer substantial dilution.

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

· warrants to purchase a total of approximately 15.4 million shares of our common stock at a current weighted average exercise price of approximately $1.40.

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

· options to purchase approximately 8.5 million shares of our common stock of a current weighted average exercise price of approximately $0.72.

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

We are not currently a party to any legal proceedings.

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

We did not submit any matters to a vote of the stockholders in the fourth quarter of 2003.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.

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, 2002 through December 31, 2003. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

	Price Range	
Period	High	Low
Fiscal Year Ending December 31, 2002 :		
First Quarter	$2.10	$0.95
Second Quarter	$1.25	$0.25
Third Quarter	$0.44	$0.11
Fourth Quarter	$0.60	$0.35
Fiscal Year Ending December 31, 2003:		
First Quarter	$1.67	$0.52
Second Quarter	$1.30	$0.82
Third Quarter	$1.11	$0.56
Fourth Quarter	$0.83	$0.60

As of March 1, 2004, we had approximately 1,300 registered stockholders of record. We have never paid any cash dividends, and currently intend to retain any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future.

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 note. 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 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 on Form 10-KSB. See "Item1.Description of Business Cautionary Note Regarding Forward-Looking Statements."

Plan of Operation

The plan of operation for going forward consists of (a) completing enrollment in the phase III orBec ® clinical trial (b) preparation and submission of a New Drug Application to the U.S. Food and Drug Administration for treatment of acute Graft-versus-Host Disease with gastrointestinal involvement; (c) initiating additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identifying a marketing and sales partner for orBec ® in the U.S. and abroad; (e) winning government funding for our biodefense programs through grant applications (f) identifying development and manufacturing partners for the biodefense program (g) transitioning the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts (h) acquiring or licensing new clinical-stage compounds for development.

In order to meet our goal of submitting a New Drug Application for orBec ® in 2004, we have implemented a number of strategies aimed at improving our clinical trial enrollment rate. 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, medical writing, etc. In addition, manufacturing of the requisite batches of drug product (registration batches) is complete and these batches are currently undergoing stability testing.

We are evaluating additional potential clinical applications for orBec ® , which include a variety of inflammatory conditions of the gut and liver, and may initiate phase II investigational clinical trials in 2004.

We have had preliminary 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 ® , and future development for potential additional indications.

The scientific development of our ricin vaccine has progressed significantly in the past year. Work to date has been funded by us through a sponsored research agreement with the University of Texas Southwestern Medical Center. It is our intent to fund further development of the vaccine through government research grants and/or a strategic partnership with a commercial partner. The initial goal for this program is to file an Investigational New Drug application with the FDA for the purposes of conducting a phase I clinical trial in healthy human volunteers. The current vaccine is being developed for intramuscular delivery, however, in parallel we are working on a formulation of the vaccine that could potentially be delivered nasally

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 previously generated by Dr. Lance Simpson at 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 the biodefense program is to supply the United States government with qualified countermeasures that will protect its citizens against ricin toxin and botulinum toxin exposure.

Finally, we are actively screening and pursuing potential licensing opportunities for clinical stage compound(s) for development.

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 development stage company and to date have not generated any material revenues from operating activities.

For the year ended December 31, 2003 we had grant revenue of $83,817 as compared to $0 in the 12 months ended December 2002. We also incurred expenses related to that revenue in 2003 of $76,197. This revenue and associated expense was due to a Small Business Innovation Research grant we received in September 2003 to further research associated with our nasally administered ricin vaccine. The total amount of this grant is $149,912.

For the 12 months ended December 31, 2003, we had a net loss applicable to common stockholders of $6,225,476 as compared to a $6,422,466 net loss applicable to common stockholders for the 12 months ended December 31, 2002, a decrease of $196,990, or 3%. Net loss applicable to common stockholders included the impact of preferred stock dividends, which totaled $936,945 in 2003, as compared to $1,456,385 in 2002. 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 2003 results reflect a shift of research and development activities from in-house proprietary research and development activities to outsourced R&D. During 2003, our research and development spending decreased by $214,063 or 7% as compared to 2002. This decrease was a result of a restructuring begun in 2002, in which we laid off our entire research staff and began outsourcing all research and development work. This has allowed us to reduce our research and development expense while increasing the efficiency in each step of the development process.

General and administrative expenses for the 12 months ended December 31, 2003 were $2,505,071 as compared to $2,988,020 for the 12 months ended December 31, 2002, a decrease of $482,949, or 16%. The 2003 total included a non-cash stock compensation charge of $954,850. This charge resulted from common stock options granted to employees and directors that were pending stockholder approval, which was received in September 2003. The decrease in administrative expense was due to a reduction in administrative staff, a decrease in outside legal expenses, and the costs associated with severance charges related to the restructuring in 2002.

Equity in earnings/(losses) from joint ventures, representing our two joint venture operations with Élan, for the 12 months ended December 31, 2002 recorded a gain of $868,859. These joint ventures terminated out in 2002, and there was no activity in 2003

Interest income for the 12 months ended December 31, 2003 was $28,707 as compared to $105,676 for the 12 months ended December 31, 2002, a decrease of $76,969 or 73%. This decrease was primarily due to the reduction in the available cash balance available for investment and the sharp reduction in interest rates during 2003.

Interest expense for the 12 months ended December 31, 2003 was $63,968 as compared to $9,103 for the 12 months ended December 31, 2002, an increase of $54,865. This increase was due to the $58,638 interest due on our note payable to Élan.

FINANCIAL CONDITION

As of December 31, 2003, we had cash and cash equivalents of $4,117,539 as compared to $4,147,164 as of December 31, 2002 and working capital of $3,287,045 as compared to $2,698,930 as of December 31, 2002. For the 12 months ended December 31, 2003, our cash used in operating activities of approximately $4.9 million, versus approximately $6 million in 2002.

We granted options to employees and directors that were conditional upon stockholder approval of an amendment to our 1995 omnibus option plan. Accordingly, a measurement date did not exist, until approval was gained at our annual stockholder meeting in September 2003. Accordingly, we recorded an expense of $954,850 in 2003. We also recorded an expense of $50,148 in 2003 for options granted to consultants.

The following table summarizes our expected expenditures under existing product development agreements and license agreements we expect to enter into pursuant to letters of intent and option agreements:

		2004 Expenditures			
Licensor	Description	1st quarter	2 nd quarter	3 rd quarter	4 th Quarter
Thomas Jefferson University	License fee	$ 10,000		$ 10,000	$ --
Thomas Jefferson University	Sponsored research	74,500	74,500	75,000	75,000
University of Texas	License fee	--	200,000	--	100,000
University of Texas	Sponsored research	25,000	25,000	--	--
Southern Research Institute	Sponsored research	120,000	--	--	--
Southern Research Institute	Patent Maintenance	15,000	15,000	15,000	15,000
Total		$ 244,500	$ 314,500	$ 100,000	$ 190,000

In 2003 we spent approximately $1.7 million on orBec®, and we anticipate spending an additional $1.3 million in 2004.

As of December 31, 2003, we had notes due of $359,067, $347,845 of which represents the entire remaining amounts payable in connection with our Newco and Innovaccines joint ventures in which we are required to make payments of $231,897 in June 2004 and $115,948 in December 2004, and $11,222 for the final monthly payment of a bank loan used to purchase equipment in 2001.

The following summarizes our contractual obligations at December 31, 2003, not including the product development and license related amounts reflected in the table above, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	2004	2005	2006
Non-cancelable operating lease obligations(1)	$ 64,502	$ 66,914	$ 52,628
Debt (2)	359,067	--	--
Total contractual obligations	$ 423,569	$ 66,924	$ 52,628

(1) 3 year lease for our corporate office signed in 2003.

(2) Debt consists of payments due to Élan as part of the dissolution of the joint ventures, and the final one month of a bank loan used to purchase equipment in 2001.

We supplemented our cash position in September 2003 with a private placement of $5.4 million, which yielded net proceeds of approximately $4.6 million after placement fees and expenses. The shares were offered at $0.796 for each share of common stock, with a warrant to purchase one share of common stock at an exercise price of $0.8756 attached to each share. We further supplemented our cash position in March 2004 with a private placement of $3.25 million netting approximately $3 million. The shares were offered at $0.79 for each share of common stock, with warrants to purchase 0.4 shares of common stock at an exercise price of $0.87 attached to each share. We believe our current cash position of $6,166,249 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least 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.

The financial statements listed in Part III Item 13, with the reports of independent certified public accountants, are included in this Form 10-KSB on pages F-1, et seq.

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

The information required by this item is contained on Form 8-K dated January 16, 2004

Item 8A. Controls And Procedures

Our Chief Executive Officer and Controller (our principal executive officer and principal financial officer, respectively) concluded, based on an evaluation of our disclosure controls and procedures performed by our management with participation of our Chief Executive Officer and Controller, that as of December 31, 2003 our disclosures, controls, and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports we filed or submit by under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Any control system, no matter how well designed and operated, can provide only reasonable (not absolute) assurance that its objectives will be met. Furthermore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

There was not any change in our internal control over financial reporting during the year ended December 31, 2003 that has materially affected or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

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

In January, 2003, General Alexander M. Haig Jr. agreed to be our Chairman of the Board, and Steve Kanzer is serving as Vice Chairman. Dr. Paul Rubin, a board member since 1996, declined to be nominated for an additional year of service at our September 15, 2003 Annual Meeting of Stockholders, and Dr. Rubin s seat was left open until February 2004, when James S. Kuo and Stuart Sedlack joined our Board of Directors. On March 15, 2003, Dr. Ralph Ellison, joined the Company as our Chief Executive Officer, President and member of the Board of Directors. The following table contains information regarding the current members of the Board of Directors and executive officers of the Company:

Name	Age	Position	Director Since
General Alexander M. Haig, Jr.	79	Chairman of the Board	2003
Steve H. Kanzer, CPA., Esq.	40	Vice Chairman of the Board	1996
Ralph M. Ellison, M.D., M.B.A.	42	Chief Executive Officer, President and Director	2003
Robert N. Brey, Ph.D.	53	Chief Scientific Officer	__
Geoff Green	30	Chief Operating Officer	__
Larry J. Kessel, M.D.	49	Director	2002
Arthur Asher Kornbluth, M.D.	43	Director	2002
James S. Kuo M.D. M.B.A.	39	Director	2004
Evan Myrianthopoulos	39	Director	2002
	43	Director	2002

Peter Salomon, M.D., FACG			
Stuart Sedlack	39	Director	2004

Alexander M. Haig, Jr., Chairman of the Board

Mr. Haig currently serves as our non-employee Chairman of the Board. 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".

Steve H. Kanzer, CPA., Esq. , Vice Chairman of the Board

Mr. Kanzer currently serves as our non-employee Vice Chairman after having served as our Interim President from June 30, 2002 through January 4, 2003 and a member of the board of directors since 1996. 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 of several private biopharmaceutical companies. He 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.

Ralph M. Ellison, M.D., M.B.A. , Chief Executive Officer and President

Dr. Ellison became our Chief Executive Officer and President in January 2003. He was a co-founder, Chief Executive Officer and Director of PolaRx Biopharmaceuticals, Inc., an oncology focused drug development company that developed Trisenox® (arsenic trioxide) for the treatment of cancer. Following the successful completion of PolaRx s pivotal phase III clinical trial, PolaRx was acquired by Cell Therapeutics, Inc., a public biopharmaceutical company based in Seattle, Washington. During his tenure as the Chief Executive Officer of PolaRx, Dr. Ellison was responsible for all aspects of PolaRx s drug development program from IND filing through the end of phase III testing. Trisenox® currently holds the record as the fastest drug developed and approved the FDA. Dr. Ellison then worked closely with Cell Therapeutics during the preparation and filing of the new drug application for Trisenox®, which was ultimately approved by the FDA for the treatment of relapsed acute promyelocytic leukemia (APL), a life-threatening cancer of the blood. Trisenox® is currently in clinical trials to treat more than 10 types of cancer, including multiple myeloma, myelodysplasia and chronic myeloid leukemia. Before to founding PolaRx, Dr. Ellison started and ran a contract research organization, which was a division of RTL, INC., a drug testing facility based in New York. At RTL he spent five years designing, implementing and completing clinical trials for both large and small pharmaceutical companies. Dr. Ellison s experience includes the development of anticancer compounds, antifungals, analgesics, anti-inflammatories, antibiotics and drug delivery systems Dr. Ellison holds a degree of Doctor of Medicine from the University of the Witwatersrand in South Africa and a Masters of Business Administration from the University of Cape Town South Africa.

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 Pharmaceuticals, which has developed a commercially successful vaccine for Haemophilius influenzae meningitis, and a vaccine for pneumonia. While at Lederle-Praxis, Dr. Brey was manager of Molecular Biology research for vaccines and project manager for development of oral vaccines from 1985 through 1993, including projects for non-typable Haemophilus, Salmonella, B. pertussis and malaria. 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 1998, 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, he held senior scientific positions at Genex Corporation from 1982 through 1986, one of the first biotechnology companies formed to exploit genetic engineering. He has been instrumental in the development of several commercial human vaccines, including HibTiter and pediatric combinations. 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. several patents in the area of vaccines. He is currently editing several theme issues of Advanced Drug Delivery Review on the topic of biodefense vaccines.

Geoff Green , Chief Operating Officer

Mr. Green was promoted to our Chief Operating Officer in November 2003. Prior to joining DOR, Mr. Green spent two and one half years in the position of Director of Clinical Affairs at Innovative Drug Delivery Systems, Inc., a specialty pharmaceutical company focused on pain therapies. There he was responsible for development and execution of the clinical programs for two late-stage therapeutic products, including a joint development program with the United States Department of Defense. Prior to that, Mr. Green spent one year in the position of Clinical Trial Manager at PolaRx Biopharmaceuticals, Inc., an oncology focused drug development company that developed Trisenox® (arsenic trioxide) for the treatment of Acute Promyelocytic Leukemia . At PolaRx, Mr. Green managed the completion of the pivotal and supportive clinical trials that provided the basis for FDA approval for Trisenox® (Cell Therapeutics, Inc., Seattle, WA). Prior to joining PolaRx, Mr. Green spent two year managing solid tumor oncology research at Memorial Sloan-Kettering Cancer Center, and has worked as a Clinical Research Associate for Contract Research Organizations such as Barton & Polansky Associates. Mr. Green holds a B.A. in Biology from Kenyon College.

Larry J. Kessel, M.D ., Director

Dr. Kessel is president of a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He graduated Magna Cum Laude with a B.S. degree from the University of Pittsburgh as an honors major in Biology and subsequently graduated with an M.D. degree from Temple Medical School. He completed a formal residency in Internal Medicine at Abington Memorial Hospital, and is board certified in Internal Medicine with added qualifications as a diplomat in Geriatric Medicine. He is an active staff attending and Clinical Instructor at Chestnut Hill Hospital (University of Pennsylvania affiliate) and Roxborough Memorial Hospital in Philadelphia Pennsylvania. Dr Kessel is a Board Reviewer for the American Board of Internal Medicine, as well as a fellow of the American College of Physicians. He also serves on the advisory board of Independence Blue Cross. Dr. Kessel presently serves as a Director of Cypress Biosciences, Inc of San Diego, California, and NovaDel Pharma Inc., of Flemington, New Jersey. He previously served on the Board of Genta Inc.

Arthur Asher Kornbluth, M.D. , Director

Dr. Kornbluth is a Board Certified Gastroenterologist and Associate Clinical Professor of Medicine at Mount Sinai Medical Center and School of Medicine in New York City, an internationally recognized leading center in the clinical research and management of inflammatory bowel disease. Dr. Kornbluth is an active clinical investigator and practicing clinician with a large practice specializing in the management of patients with complex inflammatory bowel disease. He has published extensively in peer-reviewed journals regarding the pharmacologic and biologic treatments of inflammatory bowel disease. He is the author of several book chapters regarding the diagnosis and management of inflammatory bowel disease. He is the principal author of the American College of Gastroenterology s "Ulcerative Colitis Practice Guidelines in Adults." He has taught and lectured extensively throughout the United States and has received numerous awards as a medical educator. Dr. Kornbluth received his undergraduate degree from Brooklyn College and his medical degree from Downstate Medical Center. He completed his postgraduate training in internal medicine at the Albert Einstein College of Medicine where he was chosen as chief medical resident. He performed his gastroenterology fellowship at the Mount Sinai Medical Center in New York City. He is a member of the American Gastroenterology Association, the American College of Gastroenterology, the Alpha Omega Alpha Honor Medical Society for which he was selected as both an educator and clinician at the Mount Sinai School of Medicine. He is a member of the Crohn s and Colitis Foundation of America and is a member of the that foundation s Clinical Research Alliance, has served on their Clinical Trials Protocol Review Committee and currently serves on the Clinical Research Agenda Task Force.

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

Dr. Kuo is a founder, Chairman and Chief Executive Officer of BioMicro Systems, a private nanotechnology company. Formerly, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories where he raised over $22 million in initial private funding and successfully took the company public. He has held senior business development positions at Pfizer, Myriad Genetics and Genset Corporation. 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.

Evan Myrianthopoulos , Director

Mr. Myrianthopoulos is currently the President of CVL Advisors Group, Inc., a financial consulting firm he founded that specializes in the biotechnology sector. Before founding CVL Advisors Group, Mr. Myrianthopoulos was a co-founder of Discovery Laboratories, Inc., 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. Before 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.

Peter Salomon, M.D., F.A.C.G. , Director

Dr. Salomon is a Board Certified gastroenterologist and has been in private practice with Gastroenterology Associates of South Florida for the last 11 years. An active clinical researcher in the treatment of Crohn's disease, Dr. Salomon has had several thousand patients suffering from inflammatory bowel disease. Dr. Salomon has authored numerous peer-reviewed publications on the subject of Crohn's disease and is co-author of the chapter of a leading gastroenterology textbook, Sleisinger & Fordtran's, Gastrointestinal & Liver Diseases. Dr. Salomon received his undergraduate degree from New York University in 1981 and his Medical Degree from New York University in 1985. Dr. Salomon received his training in Internal Medicine and Gastroenterology at The Mount Sinai Hospital in New York, where he also held a grant from the Crohn's and Colitis Foundation to perform research in inflammatory bowel disease. Dr. Salomon has previously been a member of the Board of Directors of Genta Inc. and PolaRx and has been a scientific advisor to Cypress Biosciences Inc.

Stuart Sedlack , Director

Mr. Sedlack spent the last six years with Élan Corporation, PLC, 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 .

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. 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, 2003, our directors, executive officers and beneficial owners of more than 10% of our capital stock have complied with all such filing requirements applicable to them, except for one late filed Form 3 for Mr. Green.

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). We have filed a copy of this Code of Ethics as Exhibit 14 to this Form 10-K. We will also make the Code of Ethics available on our website at http://www.dorbiopharma.com under the caption "Investors."

Audit Committee Financial Expert

We do not currently have an "audit committee financial expert ," as defined under the rules of the Securities and Exchange Commission, serving on our Audit Committee. We believe 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. We do not have any independent directors who would qualify as an audit committee financial expert , as defined. We believe that it has been, and may continue to be, impractical to recruit such a director unless and until we are significantly larger.

Item 10. Executive Compensation.

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2001, 2002 and 2003, to the two persons who served as our Chief Executive Officers during 2003, and one other person who served as an executive officer during the year and who s compensation exceeded $100,000 during 2003 (collectively, the "Named Executive Officers").

Summary Compensation Table

		Annual Compensation		Long term Compensation Awards
Name and Principal Position	Year	Salary($)	Bonus($)	Securities Underlying Options

Ralph Ellison	2003	$ 200,000	-	2,000,000
President & CEO (1)	2002	-	-	-
	2001	-	-	-
David Kent,	2003	$ 103,124	-	200,000
Former President & CEO(2)	2002	-	-	-
	2001	-	-	-
Robert Brey	2003	$ 155,000	-	-
Chief Science Officer (3)	2002	$ 254,600	-	-
	2001	-	-	-

(1) Dr. Ellison joined our company in March 2003.

(2) Mr. Kent joined our company in January 2003 and resigned from our company in March 2003

(3) Dr. Brey joined our company in December 2002.

The following table contains information concerning options granted to the Named Executive Officers during the fiscal year ended December 31, 2003. We have never issued Stock Appreciation Rights.

Option Grants in Last Fiscal Year

	Number of Securities Underlying Options Granted (#)	Percentage of Total Options Granted to Employees in Fiscal Year(1)	Exercise Price ($/share) (2)	Expiration Date
Ralph Ellison (3)	2,000,000	58.5%	$ 0.85	3/04/13
David Kent (4)	200,000	5.9%	$ 0.35	8/31/03
Robert Brey	-	-	-	-

(1) Based on options to purchase an aggregate of 3,420,000 shares of our common stock granted to employees and non-employee board members in the fiscal year ended December 31, 2003, including all options granted to the Named Executive Officers in all capacities.

2) The exercise price of each grant is equal to the fair market value of the Company, Inc. s common stock on the date of the grant.

(3) One third of Dr. Ellison s options vest on the date of grant, one third on the first anniversary of the grant date, and one third on the second anniversary.

4) Mr. Kent s options were granted in 2003 and expired on August 31, 2003, 6 months after his resignation.

David Kent exercised all of his options during 2003. The following table contains information concerning stock options held as of December 31, 2003 by each of the Named Executive Officers (none of which were "in-the-money" at December 31, 2003):

Fiscal Year-End Option Values

Name	Exercisable/Unexercisable	Shares Acquired Upon Exercise	Value Realized	Number of Securities Underlying Unexercised Options at 12/31/03 (#)
Ralph Ellison				1,333,333/666,667
David Kent		200,000	$ 85,000	-/-
Robert Brey				115,000/-

Employment and Severance Agreements

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 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 ptions would immediately become vested in full.

On January 4, 2003, the company entered into a two-year employment agreement with David M. Kent. Pursuant to the agreement, we agreed to pay Mr. Kent a base salary of $180,000 per year. The Company agreed to issue to him options to purchase 600,000 shares of our common stock, with one third immediately vesting and the remainder vesting over two years. In the event that Mr. Kent is terminated within the first year of employment, we would be obligated to pay him three months severance. In the event that Mr. Kent were to be terminated after the first year of employment, we would be obligated to pay him six months severance. On March 7, 2003, Mr. Kent resigned from the company and entered into a separation agreement and general release in which we agreed to pay Mr. Kent six months severance and provide him with the right to exercise the 200,000 vested options received pursuant to the his employment agreement for a period of one year.

On December 10, 2002, we entered into an employment agreement with Robert N. Brey, Ph.D., our Vice President of Research and Development. Under this agreement, we agreed to pay Dr. Brey a base salary of $155,000 per year.

Board of Directors Agreements

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 of the Company. 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.

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 yearly grants of fully vested options to purchase 50,000 shares of common stock after re-election to our Board of Directors

General Haig receives an additional $50,000 per year for consulting services outside of his service as non-executive Chairman of the Board.

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 24, 2004. 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 42,032,936 shares of common stock outstanding.

Name of Beneficial Owner	**Shares of Common Stock Beneficially Owned**	**Percent of Class**
Aries Select, Ltd.(1)	2,326,652	5.54%
Elan International Services, Ltd.(2)	3,044,556	7.24%
Lindsay A. Rosenwald, M.D.(3)	5,882,680	14.00%
Paramount Capital Asset Management, Inc.(4)	3,399,684	8.09%
OrbiMed Advisors, LLC (5)	2,911,900	6.93%
Michael A. Roth and Brian J. Stark (6)	2,531,646	6.02%
Steve H. Kanzer (7)	2,035,635	4.84%
Alexander M. Haig, Jr. (8)	2,050,000	4.88%
Ralph M. Ellison, M.D., M.B.A. (9)	1,475,857	3.51%
James S. Kuo (10)	50,000	*
Arthur Asher Kornbluth, M.D. (11)	200,000	*
Evan Myrianthopoulos (12)	386,342	*
Peter Salomon, M.D.(13)	360,000	*
Larry Kessel, M.D.(14)	404,777	*

Stuart Sedlack (15)	50,000	*
Robert Brey (16)	115,000	*
All directors and executive officers as a group (12 persons)	6,432,738	14.83%

(1) Number of shares beneficially owned includes 112,159 shares of common stock issuable upon exercise of warrants until April 16, 2008. The address of Aries Select, Ltd. is 787 Seventh Avenue, New York, NY 10019

(2) The Address of Elan International is 102 St. James Court, Flatts Smith, SC, 04 Bermuda.

(3) Lindsay A. Rosenwald, M.D., is the Chairman and Chief Executive Officer of Paramount Capital Asset Management, Inc. ("PCAM"). PCAM is the investment manager of Aries Select, Ltd and is the managing member of Aries Select I LLC. Dr. Rosenwald and PCAM share the power to vote and/or dispose of the shares held by Aries Select, Ltd. and Aries Select I LLC. The securities beneficially owned by Dr. Rosenwald include 1,392,783 shares of common stock issuable upon exercise of warrants exercisable until April 16, 2008, 66,931 shares of Common Stock issuable upon exercise of warrants exerciseable until October 2007, 2,326,652 shares beneficially owned by Aries Select I LLC, 1,052,747 shares beneficially owned by Aries Select, Ltd. and 20,284 shares beneficially owned by Aries Select II LLC. The securities beneficially owned by Dr. Rosenwald also include 682,774 shares of common stock owned by Paramount Capital Drug Development Holdings, LLC and 13,572 shares of common stock owned by each of June Street Corporation and Huntington Street Corporation. The address of Dr. Ronsenwald is 787 Seventh Avenue, New York, NY 10019.

(4) Includes the 2,326,652 of common stock shares beneficially owned by Aries Select, Ltd. and the 1,52,748 shares beneficially owned by Aries Select I LLC and 20,284 shares of common stock beneficially owned by Aries Select II, LLC. The address of Paramount Capital Asset Management, Inc. is 787 Seventh Avenue, New York, NY 10019.

(5) Includes 389,900 shares of common stock beneficially owned by Orbimed Advisors LLC, and 2,513,000 shares of common stock issuable upon the exercise of warrants until September 15, 2008. The address of Orbimed Advisors LLC is 767 Third Avenue, 30 th floor, New York, NY 10017

(6) Includes 723,327 shares of common stock issuable upon the exercise of warrants until March 12, 2009. The address of Michael A. Roth and Brian J. Stark is 10556 N Port Washington Rd. Mequon, WI 53092

(7) Includes 819,437 shares of common stock owned by Mr. Kanzer and 349,408 warrants to purchase shares of common stock and 866,800 shares of common stock issuable upon the exercise options within 60 days of March 21, 2004. The address of Mr. Kanzer is c/o Accredited Ventures, Inc., 801 Brickell Avenue, Ninth Floor, Miami, FL 33131.

(8) Includes 2,050,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2003. The address

of Mr. Haig is c/o Worldwide Associates, Inc., 4301 North Fairfax Drive, Suite 300, Arlington, Virginia 22203.

(9) Includes 142,857 shares of common stock owned by Ralph M. Ellison, M.D., MBA, 71,429 shares issuable upon the exercise of warrants until December 31, 2007, and 1,333,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2004. The address of Mr. Ellison is 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(10) Includes 50,000 options to purchase common stock within 60 days of March 15, 2004. The address of Dr. Kuo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(11) Includes 150,000 options to purchase common stock within 60 days of March 15, 2003. The address of Mr. Kornbluth is c/o Mt. Sinai Medical Center, 1751 York Avenue, New York, NY 10178.

(12) 200,000 shares of common stock issuable upon the exercise of options and 186,342 shares of common stock issuable upon the exercise of warrants, 65,454 of which expire on December 31, 2007 and 120,888 of which expire on September 16, 2008. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, Inc. 1691 Michigan Ave, Suite 435 Miami, FL 33139.

(13) Includes 350,000 shares of common stock issuable upon the exercise of options within 60 days of March 21, 2004, and 5,000 shares issuable upon the exercise of warrants exercisable until December 31, 2007. The address of Peter Salomon is c/o Gastroenterology Consultants, 951 N.W. 13 th St., Boca Raton, FL 33486.

(14) Includes 350,000 shares of common stock issuable upon the exercise of options within 60 days of March 15, 2004, and 21,429 shares issuable upon the exercise of warrants exercisable until December 31, 2007. The address of Mr. Kessel is 4114 Hain Drive, Lafayette Hill, PA 19444-1514.

(15) Includes options to purchase 50,000 of common stock within 60 days of March 15, 2004. The address of Mr. Sedlack is 1691 15 Woodland Road, Short Hills, NJ 07078 .

(16) Includes options to purchase 115,000 Shares of common stock within 60 days of March 15, 2003. The address of Mr. Brey is 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

*Less than 1%.

Equity Compensation Plan Information

As of December 31, 2003, we maintained our 1995 Amended and Restated Omnibus Incentive Plan, which was approved by our stockholders. In September 2003, our stockholders approved an amendment to our 1995 Plan to increase the number of shares available for issuance under the 1995 Plan to 10,000,000 and increased the number of shares available for issuance to a single participant under the 1995 Plan to 2,500,000.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of 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	8,496,844	$0.72	1,503,156
Equity Compensation Plans Not Approved by Security Holders	0	0	0
Total	8,496,844	$0.72	1,503,156

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 finder to introduce certain investors to the Company. Mr. Myrianthopoulos received cash compensation of approximately $62,000 and warrants exercisable for five years at approximately $0.79 per share to purchase 256,314 shares of common stock.

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 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, a 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.

In December 2002, we completed a private placement of our common stock at $0.35 per share realizing gross proceeds of approximately $1,000,000. In addition to common stock, for each share purchased investors received a warrant to purchase an additional one-half (1/2) share of common stock exercisable at $0.75 per share until the earlier of an average closing price of our common stock of $3.00 per share or December 31, 2007. 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, 285,628 shares of common stock and warrants exercisable at $0.75 per share to purchase an additional 142,571 shares. Accredited Equities, Inc., a broker-dealer owned solely by Mr. Kanzer received cash compensation of approximately $38,012 and warrants exercisable for five years at an weighted average price of $0.48 per share to purchase 161,826 shares of common stock were issued to Steve H. Kanzer and an employee of Accredited Equities in consideration for placement services rendered as a selected dealer to the placement agent of this private placement. Other subscribers in this offering included Mr. Kanzer s father and adult brother, neither of whom resides with Mr. Kanzer, and who together invested a total of $200,000 for our securities on the same terms and conditions as the other subscribers. Mr. Myrianthopoulos, a director of our company, received $15,375 in cash compensation and warrants to purchase 65,454 shares of common stock for placement services rendered to the placement agent.

Item 13. Exhibits, List and Reports on Form 8-K.

(a) The following financial statements and exhibits are filed as part of this report:

(1) Financial Statements:

(i) Independent Certified Public Accountants Report.

(ii) Consolidated Balance Sheets as of December 31, 2003 and December 31, 2002.

(iii) Consolidated Statement of Operations for the periods ended December 31, 2003 and 2002 and cumulative from February 15, 1985 (date of inception) to December 31, 2003.

(iv) Consolidated Statement of Cash Flows for the periods ended December 31, 2003 and 2002 and cumulative from February 15, 1985 (date of inception) to December 31, 2003.

(v) Consolidated Statement of Stockholders Equity for the period from February 15, 1985 (date of inception) to December 31, 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)

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 Financial Advisory Agreement between the Company and Paramount Capital, Inc. dated as of October 18, 2001. (6)

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

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

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

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

10.8 Employment agreement between the Company and Ralph Ellison dated March 13, 2003. (7)

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

10.10 License Agreement between the Company and Thomas Jefferson University

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

10.12 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University (7)

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

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

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

14.1 Code of Ethics for Financial Officers.

16.1 Letter from Ernst & Young ending their engagement.

21.1 Subsidiaries of the Company

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

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

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

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

* Management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report .

(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 for the fiscal year ended December 31, 2001, as amended.

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

(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.

(b) Reports on Form 8-K

We did not file any current reports on Form 8-K during the fourth quarter of 2003.

Item 14. Principal Accountant Fees and Services

Audit Fees

The aggregate fees billed during the years ended December 31, 2003 and 2002 by Ernst & Young LLC, our principal accountants in 2003 and 2002, 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 $151,920 and $212,250 respectively. For our 2003 year end audit, and re-audit of 2002 year end, we changed our principal accountants to Sweeney, Gates & Co. The aggregate fees billed by Sweeney, Gates & Co. for the 2003 year end audit and 2002 re-audit are $41,975and $15,795 respectively.

Audit Related Fees

Neither of our principal accountants billed us any fees during the years ended December 31, 2003 and 2002 for any assurance and related services.

Tax Fees

Our former principal accountants, Ernst and Young, billed us fees for tax compliance, tax advice and tax planning for the year ended December 31, 2002 of $13,380. Our current principal accountants Sweeney, Gates & Co. billed us $447 for tax compliance, tax advice and tax planning for the year ended December 31, 2003

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, 2003 and 2002.

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.

DOR BIOPHARMA, Inc. AND SUBSIDIARIES

(a development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

To the Board of Directors and

Stockholders

DOR BioPharma, Inc.

We have audited the accompanying consolidated balance sheet of DOR BioPharma, Inc., (a development stage company) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and cash flows for the years then ended and for the period February 15, 1985 (inception) to December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of DOR BioPharma, Inc., (a development stage company) as of December 31, 2003 and 2002 and the results of its operations and cash flows for the years then ended and the period February 15, 1985 (inception) to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

Fort Lauderdale, Florida

March 17, 2004

DOR BioPharma, Inc.
(a development stage company)
Consolidated Balance Sheets

	December 31, 2003	2002
Assets		
Current assets:		
Cash and cash equivalents	$ 4,117,539	$ 4,147,164
Receivable	20,954	
Prepaid expenses	155,844	104,333
Total current assets	4,294,337	4,251,497
	60,795	262,921

Equipment, net of accumulated amortization of $141,650 and $1,162,247		
Licenses and patent costs, net of accumulated amortization of $384,333 and $193,810	1,896,934	1,323,782
Total assets	$ 6,252,066	$ 5,838,200
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 211,587	$ 568,120
Accrued royalties	320,000	130,000
Accrued compensation and other expenses	116,638	124,480
Current portion of long-term debt	359,067	382,122
Total current liabilities	1,007,292	1,204,722
Long-term debt		347,845
Total liabilities	1,007,292	1,552,567
Stockholders 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; 126,488 and 117,118 issued and outstanding, at liquidation value	12,648,768	11,711,822
Common stock, $.001 par value. Authorized 100,000,000 shares; 34,893,765 and 26,794,642 issued, 34,721,423 and 26,622,300 outstanding	34,894	26,795
Additional paid-in capital	67,005,276	61,315,985
Common stock to be issued, 375,498 shares in 2002		436,812
Unearned compensation		(50,148)
Deficit accumulated during the development stage	(73,975,897)	(68,687,366)
	5,713,041	4,753,900
Less: Cost of 172,342 shares of common stock in treasury	(468,267)	(468,267)
Total stockholders equity	5,244,774	4,285,633

Total liabilities and stockholders equity	$ 6,252,066	$ 5,838,200

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
(a development stage company)
Consolidated Statement of Operations

	Year ended December 31,		Cumulative Period February 15, 1985 (Inception) to December 31,
	2003	2002	2003
Grant revenue	$ 83,817	$	$ 183,817
Expenses:			
Cost of revenue	76,197		162,365
Proprietary research and development	2,729,430	2,943,493	22,976,729
General and administrative	2,505,071	2,988,020	20,538,590
Write-off of acquired in-process research and development			10,181,000
Total expenses	5,310,698	5,931,513	53,858,684
Loss from operations	(5,226,881)	(5,931,513)	(53,674,867)
Other income (expenses):			
Equity in earnings (losses) of joint ventures		868,859	(22,179,091)
Other income	(26,389)		236,500
Interest income	28,707	105,676	3,600,003
Interest expense	(63,968)	(9,103)	(422,221)
Total other income (expense)	(61,650)	965,432	(18,764,809)

Net loss	(5,288,531)	(4,966,081)	(72,439,676)
Preferred stock dividends	(936,945)	(1,456,385)	(7,260,631)
Net loss applicable to common stockholders	$(6,225,476)	$(6,422,466)	$(79,700,307)
Basic and diluted net loss per share applicable to common shareholders	$ (0.21)	$ (0.29)	
Basic and diluted weighted average common shares outstanding	29,183,312	22,498,894	

The accompanying notes are an integral part of these Financial Statements

DOR BioPharma, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity

Common Stock		Common Stock to be Issued		Series B and C Convertible Preferred Stock		Additional Paid-In	(Deficit) Accumulated During the Development	Other Comprehensive	Treasury Stock		Unearned	Subscri
Shares	Par Value	Shares	Stated Value	Shares	Stated Value	Capital	Stage	Income	Shares	Cost	Compensation	Recei
non issued sh in ary at $1.50 are	667	$ 1	$		$	$ 999	$	$		$	$	$
non issued sh in er 1986 0.00	666	1				499,999						

are												
s of fair t value option of alified option d in						13,230						
non issued y 1987 0.00 are for services med e any	7					5,000						
roceeds nitial stock ng in 987 at 0 per less nce	333					1,627,833						
ualified options sed in	48					33,808					(28,188)	
tization arned ensation 7											7,425	
s of fair t value option of alified options d in						75,063						
ce at -1987	1,721	$ 2	$	$	$	2,255,932	$	$	$	$	(20,763)	$

The accompanying notes are an integral part of these Financial Statements

DOR BioPharma, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity - Continued

	Common Shares	Common Stock Par Value	Common Stock to be Issued Shares	Common Stock to be Issued Stated Value	Series B and C Convertible Preferred Stock Shares	Series B and C Convertible Preferred Stock Stated Value	Additional Paid-In Capital	(Deficit) Accumulated During the Development Stage	Other Comprehensive Income	Treasury Stock Equity Cost	Unearned Compensation	Subscription Receivable
Nonqualified stock options exercised in 1988	18	$	$	$		$	$ 256	$	$	$	$	$
Stock warrants exercised in 1988	1						12,000					
Common stock redeemed and retired in 1988	(10)						(150)					
Excess of fair market value over option price of nonqualified stock options granted in 1988							36,524					
Amortization of unearned compensation in 1988											19,113	
Nonqualified stock options exercised in 1989	71						1,060					
Common stock redeemed and retired in 1989	(12)						(175)					
Excess of fair market value												

over option price of nonqualified stock options granted in 1989						113,037						
Net proceeds from secondary public stock offering in April 1989 at $525 per share, less issuance cost	2,174	2				980,178						
Amortization of unearned compensation in 1989											1,650	
Common stock issued for cash in October 1990 through January 1991 at $9.00 per share	5,694	6				51,244						
Excess of fair market value over option price of nonqualified stock options granted in 1990						30,635						
Balance at 12-31-1990	9,657	$ 10		$	$	3,480,541	$	$		$	$	$

The accompanying notes are an integral part of these Financial Statements

DOR BioPharma, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity (Continued)

	Common Stock to be Issued	Series B and C Convertible Preferred Stock	Additional Paid-In	Accumulated During the	Other Comprehensive	Treasury Stock	Unearned	S

	Par Value	Shares	Stated Value	Capital	Stated Value	Preferred Stock Capital	Stage	Income	Shares	Cost	Compensation
91 l 0											
	2,772	$ 3	$		$	$ 24,947	$	$		$	$
0											
	15,333	15				22,985					
5											
	296,949	297				200,018					
r											
s											
						16,570					
s											
	1					1					
s											
er											
ts	66,666	66				6,230,985					

2,000	2					28						
						126,000						(126,000)
												40,750
67						57						
393,445	$ 393	$		$		$ 10,102,132	$	$		$	$	(85,250) $

The accompanying notes are an integral part of these Financial Statements

DOR BioPharma, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity Continued

Common Stock		Common Stock to be Issued		Series B and C Convertible Preferred Stock		Additional Paid-In	(Deficit Accumulated During the Development	Other Comprehensive	Treasury Stock		Unearned
Shares	Par Value	Shares	Stated Value	Shares	Stated Value	Capital	Stage	Income	Shares	Cost	Compensation

$	$	$	$	$	$	41,975	$ (300,000)	$
			(22,402)					22,402
								49,348
						76,667	(143,750)	
			(1,379)					1,379
								12,121
333,333	333		324,667					
333,333	333							