DOR BIOPHARMA INC
Form 10KSB
March 27, 2008

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

FORM 10-KSB

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

For the Fiscal Year Ended December 31, 2007

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission File No. 000-16929

DOR BIOPHARMA, INC.
(Exact name of small business issuer as specified in its charter)

DELAWARE	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
850 Bear Tavern Road, Suite 201 Ewing, NJ	08628
(Address of principal executive offices)	(Zip Code)

(609) 538-8200
(Issuer's telephone number, including area code)

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	OTCBB

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

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

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

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

Issuer's revenues for its most recent fiscal year: $1,258,017

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $16,000,000 (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), based on the closing price of the registrant's common stock as reported on the Over-the-Counter Bulletin Board on March 24, 2008.

At March 24, 2008, 100,299,378 shares of the registrant's common stock were outstanding.

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

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PART I

Item 1. Description of Business.

This Annual Report on Form 10-KSB contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this report that could cause actual results to differ materially from those indicated in any forward-looking statements, including those set forth in "Risk Factors" in this Annual Report. See "Cautionary Note Regarding Forward Looking Statements."

A. Overview

We were incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. On September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® (oral beclomethasone dipropionate) with the FDA for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"). On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicines Evaluation Agency (the "EMEA") for orBec®, which is currently under review. We anticipate receiving the EMEA's official opinion to our MAA in the first half of 2008.

On October 18, 2007, we received a not approvable letter from the U.S. Food and Drug Administration (the "FDA") in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. We subsequently requested on October 19, 2007, an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's Special Protocol Assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin a new Phase 3 clinical trial for the treatment of GI GVHD in the second half of 2008.

We maintain two active segments: BioTherapeutics and BioDefense. Our business strategy is to: (a) work with the FDA on the design of new clinical trials in GI GVHD; (b) seek a development and marketing partner for orBec® for territories both inside and outside of the US; (c) prepare for the potential marketing approval of orBec by the EMEA; (d) conduct a prophylactic use clinical trial of orBec® for the prevention of GI GVHD; (e) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis and Crohn's disease; (f) reinitiate development including manufacturing of our other biotherapeutics products namely LPMTM-Leuprolide, and OraprineTM; (g) secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts, and procurements; (h) explore acquisition strategies under which the Company may be acquired by another company with oncologic or gastrointestinal symmetry; (i) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area; and (j) acquire or in-license new clinical-stage compounds for development.

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BioTherapeutics Overview

Through our BioTherapeutics Division, we are in the process of developing oral therapeutic products to treat unmet medical needs. Our lead product, orBec®, has been evaluated in a randomized, multi-center, double-blinded, placebo-controlled pivotal Phase 3 clinical trial for the treatment of GI GVHD, a serious and life-threatening gastrointestinal inflammation associated with allogeneic hematopoietic cell transplantation ("HCT"). While orBec® did not achieve statistical significance in time to treatment failure through Day 50 (p-value 0.1177), the primary endpoint of its pivotal trial, there was a positive trend observed and it did achieve statistical significance in other key outcomes such as median time to treatment failure through Day 80 (p-value 0.0226). Most importantly, it demonstrated a statistically significant survival advantage in comparison to placebo at 200 days post-transplantation (p-value 0.0139) and at one year post-randomization (p-value 0.04).

We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006. We also filed an MAA with the EMEA on November 3, 2006, which was validated on November 28, 2006 and is currently under review. On October 18, 2007, we received a not approvable letter from the FDA for orBec®. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing & controls information as part of the not approvable letter. On October 19, 2007, we requested an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's Special Protocol Assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008.

On February 15, 2008, we announced that we entered into a Letter of Intent with BL&H Co. Ltd. ("BL&H"), a specialty pharmaceutical company based in Seoul, Korea, pursuant to which BL&H will act as our Sponsor with regard to the administration of a Named Patient Program ("NPP") for orBec® to patients suffering from acute GI GVHD in South Korea. The NPP is a compassionate use drug supply program administered by the Korea Orphan Drug Center (KODC) under which medical practitioners can legally supply investigational drugs to their patients who qualify. Under this program, investigational drugs can be administered through KODC to patients who are suffering from serious illnesses until the drug is approved by the Korea Food & Drug Administration. BL&H and our Company will share revenues generated by sales of orBec® through the NPP. We will manufacture and supply orBec® to BL&H, while BL&H will be responsible for all distribution costs in South Korea. We expect to receive modest revenues from these programs in the second half of 2008.

On November 28, 2007, we announced that we entered into a Letter of Intent with Orphan Australia Pty Ltd. ("Orphan Australia"), a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which Orphan Australia will act as our sponsor with regard to the administration of a Named Patient Access Program ("NPAP") for orBec® to GI GVHD patients in Australia, New Zealand and South Africa. The NPAP is a compassionate use drug supply program administered by Australia's Therapeutic Goods Administration ("TGA"), under which medical practitioners can legally supply investigational drugs to their patients who qualify. The program enables a medical practitioner to access not yet approved medicines for seriously ill patients with prior notification to the TGA. Both we and Orphan Australia, acting as sponsor for the program, will receive revenue for supplying orBec® under the NPAP. New Zealand and South Africa also have similar access mechanisms for supply under a "Named Patient" basis. We expect to receive modest revenues from these programs in the second half of 2008.

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On September 12, 2007 we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from the National Institute of Health ("NIH") to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of gastrointestinal (GI) radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this work is successful and it will enhance the value of our orBec®/oral BDP program. The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studies will compare overall survival and markers of intestinal cell regeneration when the drug regimens are added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC.

On July 12, 2007, we announced that patient enrollment commenced in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GI GVHD after allogeneic HCT with myeloablative conditioning regimens. The trial is being conducted by Paul Martin, M.D., at the FHCRC in Seattle, Washington and is being supported, in large part, by an NIH grant. We will not receive any monetary benefit from this grant. The Phase 2 trial will seek to enroll up to 138 (92 orBec® and 46 placebo) patients. The primary endpoint of the trial is the proportion of subjects who develop acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. Patients in the orBec® group will begin dosing at the start of the conditioning regimen and continue through day 75 following HCT. Trial enrollment is expected to be completed in the first half of 2009.

In April 2007, we initiated our next pipeline development program in the biotherapeutics area: our LPM™ (Lipid Polymer Micelle) drug delivery system to enhance the intestinal absorption of water-soluble drugs/peptides, which are ordinarily poorly absorbed. We restarted preclinical formulation work on LPM™ in 2007 after a period of approximately four years. This system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides that are not readily absorbed in the GI tract. Preclinical animal pharmacokinetic ("PK") data have demonstrated high relative bioavailability of the therapeutic peptide drug leuprolide in the 20-40% range. Leuprolide is both a candidate drug for further development in several indications, such as prostate cancer and endometriosis as well as a prototype for development of other similar non-absorbable, but water soluble drugs. The mechanism for absorption by LPM™ is thought to involve the passive uptake through the opening of paracellular channels in intestinal epithelial tissue.

BioDefense Overview

In collaboration with the University of Texas Southwest Medical Center and Thomas Jefferson University, we are developing vaccines to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits induce antibodies that neutralize the toxins from which they are derived. Through exclusive licenses with the universities, we have secured important intellectual property rights related to these vaccines. Both of these are considered bioterrorism threats by the U.S. Department of Homeland Security, the National Institute of Allergy and Infectious Diseases ("NIAID"), Department of Defense ("DOD") and Centers for Disease Control and Prevention ("CDC"). In fact, the threat of ricin toxin as a biological weapon of mass destruction has been highlighted along with anthrax in a recent Federal Bureau of Investigation Bioterror report released in November

2007, which says, “Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations.” We are developing our biodefense countermeasures for potential U.S. government procurement pursuant to the Project BioShield Act of 2004, which provides incentives to industry to supply biodefense countermeasures to the Strategic National Stockpile.

The development of RiVaxTM, our ricin toxin vaccine, has progressed significantly. In September 2006, we received a grant of approximately $5.2 million from NIAID, a division of the NIH, for the continued development of RiVax™, a recombinant vaccine against ricin toxin. The RiVax™ grant will provide approximately $5.2 million over a three year period to fund the development of animal models which will be used to correlate human immune response to the vaccine with protective efficacy in animals. This is necessary for ultimate licensure by the FDA, when human efficacy vaccine trials are not possible. This new grant also supports the further biophysical characterization of the vaccine containing a well-characterized adjuvant that is needed to enhance the immune response to recombinant proteins. These studies will be required to assure that the vaccine is stable and potent over a period of years. A prototype version of RiVax™ has been evaluated in a Phase 1 clinical trial and was shown to be safe and effective, while also inducing ricin neutralizing antibodies as confirmed in subsequent animal studies.

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On January 29, 2008, we announced that we have successfully achieved a two-year milestone in the long-term stability program of the key ingredient of RiVax™, a recombinant subunit vaccine against ricin toxin. RiVax™ is intended to protect against exposure to ricin toxin that might result from the purposeful release of ricin in an aerosolized form or as a poisonous contaminant in food or water. The results of the two-year analysis, undertaken as part of the formal stability program, demonstrate that the immunogen component of RiVax™, a recombinant derivative of the ricin A chain, is stable under storage conditions for at least two years without loss of its natural configuration or the appearance of any detectable degradation products. A vaccine is considered by many to be the best way to prospectively protect populations at risk of exposure against ricin toxin. As this vaccine would potentially be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack, the activity of the vaccine must be maintained over a period of years under stockpile storage conditions.

Robust stability is one of the key factors stipulated by the Biomedical Advanced Research and Development Authority (“BARDA”) for vaccines to be included in the Strategic National Stockpile. BARDA has placed a priority on stability and a rapid onset of immunity in no more than two vaccine doses as the stability and efficacy targets for vaccines under development for both category A and category B vaccines. BARDA has recently issued a Request for Procurement (“RFP”), entitled "Biodefense Vaccine Enhancement," to which we have submitted an application for RiVax™. BARDA is a new agency within the U.S. Department of Health and Human Services (“HHS”) established to implement acquisition under the Project BioShield Act and to foster the development of vaccines and countermeasures such as RiVax™ that have achieved milestone hurdles, and are candidates for continued development. To this end, BARDA has solicited proposals in a number of key areas, including development of vaccines for categories A and B that have enhanced stability properties that address long-term storage and the benefit of rapid onset of immunity. We have submitted an application for RiVax™ for the BARDA RFP. We regularly apply for biodefense grants, as well as RFPs, when appropriate, from NIH and other applicable governmental bodies that support biodefense.

On November 15, 2007, we announced that we entered into a Cooperative Research and Development Agreement with the Walter Reed Army Institute of Research (“WRAIR”) to provide additional means to characterize the immunogenic protein subunit component of RiVax™, our preventive vaccine against ricin toxin. The agreement will be carried out at the Division of Biochemistry at WRAIR and will encompass basic studies to reveal the underlying protein structure that is important in inducing human immune responses to ricin toxin. Ricin toxin is an easy to manufacture toxin that poses a serious threat as a bioweapon, primarily by inhalation. Some of the features that are critical to induce protective immune responses by vaccination with RiVax™ include structural determinants in the core and the surface of the protein. The purpose of the agreement is to obtain data to correlate protein structure with induction of protective immunity and long-term stability of the protein. These studies will involve comparison to structures of similar natural and recombinant proteins. RiVax™ induces antibodies that appear primarily in the blood of animals and humans. Some of these antibodies recognize determinants on the protein that are dependent on the conformation of the protein and may be involved in biological activity. Overall, antibodies in the blood are correlated to protection against exposure when the toxin enters the circulatory system or when it comes into contact with lung surfaces, where the major effects lead to severe inflammation, tissue necrosis and death. RiVax™ induces such antibodies in humans as well as other animal species. Lieutenant Colonel Charles B. Millard, Ph.D., Director of the Division of Biochemistry at WRAIR, will lead the studies to be conducted at WRAIR, which will include X-ray crystal analysis to determine the structural parameters of the RiVax™ vaccine. We will not receive any monetary benefits from this agreement. We will take part in evaluating the data that was found by WRAIR’s studies which they are funding. If successful, this will enhance the value of our RiVax™ product and assist with continuing to move the program forward.

Our vaccine against botulinum neurotoxin, BT-VACC™, is a mucosally administered vaccine that protects against exposure to botulinum neurotoxins. Botulinum neurotoxin is the most toxic natural toxin known to man and is on the NIAID Category A list of biothreats. Based on promising preclinical results that demonstrate induction of protective immune responses via oral or intranasal vaccination, we anticipate that BT-VACC™ can be developed as either a standalone vaccine or administered as a booster to the current injected vaccines. We are developing BT-VACC™ to be administered by the mucosal route since such vaccines induce more complete protection than injected vaccines and are

thought to confer better protection against aerosol or oral exposure to botulinum neurotoxin. Since mucosally administered formulations can be given without needles and trained personnel, we expect that BT-VACC™ will be poised for rapid distribution and vaccination for military use or civilian vaccination in response to bioterrorism. Any vaccine against botulinum toxin will have to be composed of multiple antigens representing several natural serotypes. At this point, we have demonstrated that combinations of three serotypes can induce protective immune response in animals. The three serotypes are A, B, and E, which represent the most common of the botulinum serotypes and the ones most likely to be used as bioweapons. Our plans are to focus on development of the oral vaccine concept using formulation technology that permits increased contact of the antigen with immune inductive sites in the GI tract, and alternatively develop the A-B-E trivalent vaccine as a nasal spray vaccine. In conjunction with Dowpharma, a business unit within the Dow Chemical Company, we have demonstrated that it will be feasible to manufacture the required antigens in a bacterial host (P. fluorescens), and are anticipating developing purification processes for each antigen. BT-VACC™ is covered by issued and pending U.S. patents.

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B. BioTherapeutics Division

1. 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. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the Prescription Drug User Fee Act ("PDUFA"), the FDA was to complete its review of all materials related to orBec® by July 21, 2007. Additionally, on May 9, 2007, the Oncologic Drugs Advisory Committee ("ODAC") appointed by the FDA voted that the data supporting orBec® did not show substantial evidence of efficacy by a margin of 7 to 2 for the treatment of GI GVHD. The FDA was not bound by ODAC's recommendations, but it took the panel's advice into consideration when reviewing the NDA for orBec®.

On July 18, 2007, we received notification from the FDA that the PDUFA date for the FDA's review of the NDA for orBec® was extended to October 21, 2007. The extension was the result of our July 13, 2007 provision of supplemental information to the orBec® NDA. This information was requested by the FDA at a June 13, 2007 NDA review meeting. According to FDA policy, the submission of this supplemental information was classified as a major amendment, extending the new PDUFA date for the orBec® NDA at October 21, 2007.

On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing & controls information as part of the not approvable letter. On October 19, 2007, we requested an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well-designed, well-executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's Special Protocol Assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in second half of 2008.

We also filed an MAA with the EMEA on November 3, 2006, which was validated on November 28, 2006 and is currently under review. We anticipate receiving the EMEA's official opinion to our MAA in the first half of 2008. We have assembled an experienced team of consultants and contractors who worked on all aspects of the NDA and MAA preparation, including data management, data analysis, and biostatistics medical writing.

We anticipate the market potential for orBec® for the treatment of GI GVHD to be approximately 60 percent of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We are evaluating partnering opportunities in the U.S. and abroad in an effort to seek support for future clinical development of orBec® for the treatment of GI GVHD. We also intend to seek a partner for the other potential indications of orBec® and oral BDP.

On July 12, 2007, we announced that patient enrollment had commenced in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic HCT with myeloablative conditioning regimens. The Phase 2 clinical trial is supported in part by an NIH grant awarded to the FHCRC. We will not receive any monetary benefit from this grant. The protocol is entitled "A Phase 2 study to

evaluate the efficacy of oral beclomethasone dipropionate for prevention of acute GVHD after hematopoietic cell transplantation with myeloablative conditioning regimens." The study will enroll a total of 138 patients with 92 subjects in the orBec® arm and 46 subjects in the placebo arm. The principal investigator of the trial is Paul Martin, M.D., of the FHCRC and a Professor of Medicine at Washington University. Patients will be treated with orBec® or placebo at the start of their conditioning regimen and will continue to be treated for 75 days after transplantation. The objective of the trial is to test the hypotheses that prophylactic administration of orBec® can prevent the incidence and/or reduce the severity of acute GVHD, therefore, decreasing the need for use of high dose systemic steroid treatment after allogeneic HCT. Completion of patient enrollment in this trial is targeted for the first half of 2009.

On September 12, 2007, we announced that our academic partner, FHCRC, received a $1 million grant from the NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of gastrointestinal (GI) radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this study is successful and it enhances the value of our orBec®/oralBDP program. The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three clinical-grade drugs including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infections that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, will benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism.

In addition to the preclinical studies in radiation exposure being conducted at FHCRC, we plan to begin a Phase 1/2 clinical trial in radiation enteritis patients in the second half of 2008.

We also plan to initiate a Phase 2 clinical trial in Chronic GVHD in the second half of 2008. Chronic GVHD can begin anytime during or after the third month post-transplantation. About 60 percent of patients who receive an allogeneic transplant and are alive at day 100 post-transplantation will develop chronic GVHD. Chronic GVHD can range from mild to life-threatening. Some transplantation survivors have problems with chronic GVHD for many years.

orBec® Comprehensive Long-Term Mortality Results

Among the data reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, orBec® showed continued survival benefit when compared to placebo one year after randomization in the pivotal Phase 3 clinical trial. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, hazard ratio 0.54, 95% CI: 0.30, 0.99, p=0.04, stratified log-rank test). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p=0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to orBec® compared with placebo (hazard ratio 0.63, p=0.03, stratified log-rank test).

200 Days Post Transplantation Mortality Results

	Phase 3 trial		Phase 2 trial	
	orBec®	Placebo	orBec®	Placebo
Number of patients randomized	62	67	31	29
Number (%) who died	5 (8%)	16 (24%)	3 (10%)	6 (21%)
Hazard ratio (95% confidence interval)	0.33 (0.12, 0.89)		0.47 (0.12, 1.87)	
Death with infection*	3 (5%)	9 (13%)	2 (6%)	5 (17%)
Death with relapse*	3 (5%)	9 (13%)	1 (3%)	4 (14%)

*Some patients died with both infection and relapse of their underlying malignancy.

In the pivotal Phase 3 clinical trial, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, “the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p=0.03, Wald chi-square test).” Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely time to treatment failure through Day 50 (p=0.1177), orBec® did achieve statistical significance in other key outcomes such as reduction in the risk of treatment failure through Day 80 (p=0.0226) and, most importantly, demonstrated a statistically significant long-term survival advantage compared with placebo. The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the pivotal Phase 3 trial; three patients (10%) who had been randomized to orBec® had

died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significantly different. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

In the pivotal Phase 3 trial, orBec® achieved these mortality results despite the fact that there were more "high risk of underlying cancer relapse" patients in the orBec® group than in the placebo group: 40, or 65%, versus 29, or 43%, respectively. There was also an imbalance of non-myeloablative patients in the orBec® treatment group, 26, or 42%, in the orBec® group versus 15, or 22%, in the placebo group, putting the orBec® group at a further disadvantage. In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of mortality 200 days post-transplantation.

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Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the pivotal study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo.

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of GI GVHD to be approximately 60 percent of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

We are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec® in the U.S. and abroad, including evaluating acquisition opportunities of the entire company. We also may seek a partner for the other potential indications of orBec®. When and if approved, we are also considering the possibility of a commercial launch of orBec® by ourselves in the U.S.

On January 3, 2007, we received $3 million under a non-binding letter of intent with Sigma-Tau Pharmaceuticals, Inc. (Sigma-Tau), which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other DOR pipeline compounds until March 1, 2007. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. Sigma Tau has both prescription and consumer products in the metabolic, oncology, and renal markets.

Under the terms of the letter of intent, Sigma-Tau purchased $1 million of our common stock at the market price of $0.246 per share, representing approximately four million shares. Sigma-Tau paid an additional $2 million in cash, which was to be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because no agreement was reached by March 1, 2007, we were obligated to return the $2 million to Sigma-Tau by April 30, 2007. On February 21, 2007, Sigma-Tau relinquished its exclusive rights under the letter of intent with regard to acquisition discussions. On June 1, 2007 we returned the $2 million to Sigma Tau without interest.

Cost and Development of our Programs

Our research and development expense may vary significantly from quarter to quarter depending on product development cycles, the timing of clinical studies and whether we or a third party are funding development. We intend to focus on long-term growth prospects, and, therefore, may incur higher than expected research and development expenses in a given period rather than delay clinical activities. These variations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations. Our long-term strategy is dependent upon the successful development of our products and their successful commercialization. A project can fail or be delayed at any stage of development, even if each prior stage was completed successfully, which could jeopardize our ability to recover our investment in the product. Some of our development projects may not be completed successfully or on schedule. Many of the factors which may cause a product in development to fail or be delayed may be beyond our control, such as difficulty in enrolling patients in clinical trials, the failure of clinical trials, lack of sufficient supplies or raw materials, inability to supply the subject product or technology on a commercial scale on an economical basis, and changes in regulations.

We estimate our development costs for our BioTherapeutics programs to be approximately $3.5 million for 2008. These costs are primarily for advancement and commencement of clinical studies for our BioTherapeutics programs. We estimate that our development costs for our BioDefense programs to be approximately $2.7 million for 2008. All costs associated with our biodefense programs will be funded by our NIH and SBIR grants.

Research and Development

Since 2000, we have incurred expenses of approximately $15,000,000 in the development of orBec®. Research and development costs for orBec® totaled $2,288,615 in 2007 and $3,060,778 in 2006.

To build upon the promising results obtained during development of orBec® for the treatment of GI GVHD, we are pursuing a development program targeting the prevention of acute GVHD. This program is a Phase 2 single center trial that is being conducted at FHCRC. This study will enroll approximately 138 patients and is designed to assess the safety and efficacy of orBec® in preventing acute GVHD after allogeneic hematopoietic stem cell transplantation. We initiated this Phase 2 clinical trial in the third quarter of 2007. If the data from this clinical trial demonstrate positive results, the potential market for orBec® would expand to potentially include all patients in the U.S. who undergo allogeneic hematopoietic stem cell transplantation and who are at risk for developing acute GVHD.

About Graft-versus-Host Disease

Graft-versus-Host Disease occurs in patients following allogeneic bone marrow transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 60% of the more than 10,000 annual allogeneic transplantation patients in the United States will develop some form of acute GI GVHD.

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

About Allogeneic Bone Marrow/Stem Hematopoietic Cell Transplantation (HCT)

Allogeneic hematopoietic cell transplantation (“HCT”) is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HCT procedure, hematopoietic stem cells are harvested from a closely matched relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or intense immunosuppressive conditioning therapy. The curative potential of allogeneic HCT is now partly attributed to the so-called GVL (graft-versus-leukemia) or graft-versus-tumor effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, the establishment of unrelated donor programs, the use of cord blood as a source of hematopoietic stem cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of high-dose chemotherapy. Based on the latest statistics available, it is estimated that there are more than 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the current annual rate of increase in these procedures are as high as 20%. High rates of morbidity and mortality occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplantation has also been used as curative therapy for several genetic disorders, including immunodeficiency syndromes, inborn errors of metabolism, thalassemia and sickle cell disease. The primary toxicity of allogeneic HCT, however, is GVHD in which the newly

transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

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2. Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec® 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 GI GVHD following HCT, as well as GVHD which also occurs following organ allograft transplantation. We initiated a Phase 2 trial of orBec® in the prevention of acute GVHD in the third quarter of 2007. In addition, we are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Ulcerative Colitis, Crohn's Disease, Lymphocytic Colitis, Irritable Bowel Syndrome, among other indications.

3. Other Products in BioTherapeutics Pipeline

The following is a brief description of other products in our pipeline. Due to past resource limitations, we have focused our R&D efforts on orBec®, RiVax® and BT-VACCTM. However, we have re-initiated development of some of these products, all of which are currently available for licensing or acquisition. These products consist of drug delivery technologies that facilitate the oral delivery of hydrophobic and hydrophilic drugs, including peptides, and macromolecules such as leuprolide. The drug delivery systems, LPM™, LPE™, PLP™, were developed internally and we have submitted and pursued patents on these products. We acquired an oral form of the immunosuppressant azathioprine (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. We also acquired patent applications on oral azathioprine from Dr. Joel Epstein of the University of Washington. We conducted a Phase 1 study that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease.

LPMTM - Leuprolide

In April 2007, we announced the initiation of a development program with our Lipid Polymer Micelle ("LPM™") oral drug delivery technology. The LPM™ system is a platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in preclinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide hormone drug leuprolide.

In preclinical studies, our LPM™ delivery technology significantly enhanced the ability of leuprolide, to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone (GnRh), which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising preclinical data, we anticipate preparing for a Phase 1 study in humans in 2008 to confirm these findings.

The LPM™ system is a proprietary oral delivery platform technology that utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a "reverse micelle" that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

We expect to validate the LPM platform technology using leuprolide as the target peptide. We expect to perform a Phase 1 PK study with a version of LPM that prolongs the absorption of leuprolide and results in high relative

bioavailability. An oral version of leuprolide may also provide a significant advantage over the currently marketed "depot" formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide sales of approximately $1.8 billion in 2006. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

Research and Development

In preclinical studies, we have been able to demonstrate significant intestinal absorption enhancement of both LPM™-Leuprolide and Leuprolide in comparison to solution formulations of the peptides in rats and dogs. Based on these promising preclinical data, we plan further development of LPM™-Leuprolide. Because of the wide applicability of Leuprolide in other medical conditions, such as in prostate cancer, it is possible that an oral formulation will prove to be acceptable for other indications. Obtaining marketing approval for further indications will require additional clinical testing in patients. In addition to LHRH and agonists, we plan to evaluate other classes of water-soluble drugs/peptides with the LPM™ system when resources permit.

Cost and Development analysis for LPM™ Leuprolide

We have completed proof of concept studies in rats and dogs. We first plan to conduct a small Phase 1 clinical PK study to compare the absorption of an enteric-coated gelatin capsule of LPM™-Leuprolide with an injected formulation. We anticipate initiating this trial in the second half of 2008. Being able to move forward with later stage clinical trials is highly dependent upon the results from the Phase 1 trial interactions with the FDA. We will have to raise additional funds in order to conduct later phase clinical trials. This may require partnering of the product at various stages during development.

The costs that we have incurred to develop LPMTM-Leuprolide since 2000 were approximately $1,300,000. Research and development costs for LPMTM-Leuprolide totaled $38,254 in 2007 and $5,679 in 2006. These costs are mainly legal costs in connection with maintenance of our patent positions and for preclinical formulation work.

OraprineTM

We anticipate that an orally administered version of the immunosuppressant drug azathioprine may have a significant role in treating inflammatory diseases of the oral cavity. Further, an orally administered drug may provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine that would have utility in elderly patients. OraprineTM is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Joel Epstein at the University of Washington that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from GVHD. Oral GVHD can occur in up to 70% of patients who have undergone bone marrow/stem cell transplantation despite treatment with other immunosuppressive drugs such as prednisone, methotrexate, tacrolimus, and cyclosporine. 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.

On September 25, 2007, we announced a Notice of Allowance of patent claims based on U.S. Patent Application #09/433,418 entitled "Topical Azathioprine for the Treatment of Oral Autoimmune Diseases." Concurrently, the patent has also been issued by the European Patent Office with the serial number EP 1 212 063 B1. This patent family specifically includes claims for treatment and prevention of oral GVHD with locally or topically applied azathioprine.

Research and Development

Our research and development plans are primarily focused on obtaining sufficient stability data on the reformulated product to allow us to proceed into additional humans trials. We propose to position Oraprine™ initially in the market as a specialty generic product to be used by transplant or rheumatoid arthritis patients who cannot swallow medicines in tablet form. We anticipate that the market will include the pediatric transplant populations, the elderly, and cancer patients who have received stem cell transplants. Therefore, we plan to file an abbreviated new drug application ("ANDA") for Oraprine™ based on small bioequivalence trials in healthy humans accompanied by new manufacturing data on the characterization of the stable formulation and to obtain approval for use in pediatric patients when resources permit. If approval is received, we then plan to conduct additional studies when resources permit in patients with chronic oral ulcerations, such as oral graft versus host disease (GVHD) and other autoimmune diseases of the mouth and upper esophagus, where topical application of AZA may have an advantage in treatment of mucosal lesions whose underlying cause is mediated by activated T cells. The FDA has granted orphan drug status for our application for use of Oraprine™ for the treatment of oral GVHD.

We plan to begin development of a stable liquid formulation, which is planned to be completed before the end of 2008, with concurrent initiation of stability assessments. A series of bioequivalence studies are to be initiated in adults and children by 2009, with trials to establish safety and efficacy in pediatric juvenile rheumatoid arthritis patients. The assumption in the above scenario is that we will develop the drug on our own without partners and market the drug through our own sales force. The premise behind the development of the drug under the ANDA strategy is that the technical objective of achieving a stable liquid formulation can be achieved in the light of the known chemical instability of azathioprine. Thus, the next major milestone is the completion of formulation development with demonstration of acceptable drug stability. It is possible that, based on achievement of any of the milestones, we will achieve revenue through outlicensing and partnering arrangements.

The costs that we have incurred to develop Oraprine™ since 2000 were approximately $400,000. Research and development costs for Oraprine™ totaled $5,100 in 2007 and $6,996 in 2006. These costs are mainly legal costs in connection with maintenance of our patent positions.

LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs

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

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C. BioDefense Programs

In collaboration with the University of Texas Southwest Medical Center and Thomas Jefferson University, we are developing vaccines 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 nontoxic subunits of the native toxins. These subunits induce antibodies that neutralize the toxins from which they are derived. Through exclusive licenses with these Universities, we have secured intellectual property rights for these vaccines.

1. RiVaxTM - Ricin Toxin Vaccine

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

The development of RiVaxTM, our ricin toxin vaccine, has progressed significantly since 2003. In September 2006, we received a grant of approximately $5.2 million from NIAID, a division of the NIH, for the continued development of RiVax™, a recombinant vaccine against ricin toxin. The RiVax™ grant has provided approximately $5.2 million over a three year period to fund the development of animal models which will be used to correlate human immune response to the vaccine with protective efficacy in animals. This is necessary for ultimate licensure by the FDA, when human efficacy vaccine trials are not possible. This new grant also supports the further biophysical characterization of the vaccine containing a well-characterized adjuvant that is needed to enhance the immune response to recombinant proteins. These studies will be required to assure that the vaccine is stable and potent over a period of years. A prototype version of RiVax™ has been evaluated in a Phase 1 clinical trial and was shown to be safe and effective, while also inducing ricin neutralizing antibodies as confirmed in subsequent animal studies.

We also announced in January 2008 that we have successfully completed a two year interim analysis in the long-term stability program of the key ingredient of RiVax™. The results of interim analysis in the formal stability program demonstrate that the immunogen component of RiVax™, a recombinant derivative of the ricin A chain, is stable under storage conditions for at least two years without loss of its natural configuration or the appearance of any detectable degradation products. Since there is no therapeutic available to treat exposure to ricin toxin, a vaccine against ricin is considered by many the best way to prospectively protect certain human populations who are at risk of exposure. Since this vaccine would presumably be added to the Strategic National Stockpile and dispensed in the case of a terrorist attack, the activity of the vaccine must be maintained over a period of years under potential stockpile storage conditions.

Our academic partner, the University of Texas Southwestern Medical Center led by Dr. Ellen Vitetta, completed a Phase 1 safety and immunogenicity trial of RiVaxTM in human volunteers. The results of the Phase 1 safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. Despite the absence of an adjuvant, antibodies were present in the blood of several volunteers for as long as 127 days after their last vaccination. The functional activity of the antibodies was confirmed by transferring serum globulins from the vaccinated individuals along with active ricin toxin into sensitive mice, which then survived subsequent exposure to ricin toxin. The outcome of the study was published in the Proceedings of the National Academy of Sciences in January 2006. In January 2005, we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. In July 2006, we announced the successful completion of the current Good Manufacturing Practices (cGMP) milestone for the production of RiVaxTM.

In July 2007, we announced that the Office of Orphan Products Development (OOPD) of the FDA has awarded a development grant for the further clinical evaluation of RiVaxTM. The grant was awarded to the University of Texas Southwestern Medical Center, to further the development of RiVaxTM. We will not receive any monetary benefits from this grant; however, the successful completion of this work will enhance the value of our RiVaxTM program and continue to move it forward. The principal investigator for the project is Dr. Vitetta, Director of the Cancer Immunobiology Center at the University of Texas Southwestern. The award totals approximately $940,000 for three years and is to be used for the evaluation of an adjuvant for use with the vaccine. Typically, awards made by the OOPD are to support clinical trials for development of products that address rare diseases or medicines that would be used in numerically small populations. We plan on initiating a non-human primate study and endeavor to begin a human clinical trial with RiVaxTM in the first half of 2008.

We believe that RiVaxTM is at a sufficiently advanced state of development for the awarding of further development contracts from other agencies and branches of the government. For example, in 2006 the Department of Health and Human Services created a separate agency, BioDefense Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services. BARDA manages Project BioShield to procure countermeasures and vaccines and is the agency now responsible for advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents. The purpose of BARDA is to take over where NIH has left off in the transition from research and development to advanced development and clinical testing. In addition, BARDA is responsible for establishing priorities for civilian biodefense. BARDA has placed a priority on stability and a rapid onset of immunity in no more than two vaccine doses as the stability and efficacy targets for vaccines under development for both category A and category B vaccines. BARDA has recently issued an RFP, entitled “Biodefense Vaccine Enhancement,” to which we have submitted an application for RiVaxTM. We expect to continue to respond to RFPs that may arise within BARDA and other branches of the government.

Research and Development

RiVax™ is being developed as a conventional vaccine, to be administered by injections. We have secondary plans to develop RiVax™ as a nasally administered vaccine for the medical purpose of stimulating immunity in the lungs to prevent toxicity by the anticipated route of exposure through inhalation if ricin were to be used as a bio-weapon. At this point we are focusing our efforts on the development of the injectable vaccine, and have deferred the development of a nasal vaccine.

Cost and Development analysis for RiVax™

The costs that we have incurred to develop RiVax™ since 2002 were approximately $6,600,000. Research and development costs for RiVax™ totaled $1,350,364 in 2007, of which $897,470 was for costs reimbursed under the NIH grant and $2,130,516 in 2006, of which $1,128,257 was for costs reimbursed under this grant.

2. BT-VACCTM - Botulinum Toxin Vaccine

Our botulinum toxin vaccine, called BT-VACC™, stems from the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. The vaccine is being developed as an oral or intranasal formulation to be given as a primary immunization series or as oral or nasal booster to individuals who have been primed with an injected vaccine. Botulinum toxin is the product of the bacteria Clostridium botulinum. Botulinum toxin is the most poisonous natural substance known to man. Botulinum toxin causes acute, symmetric, descending flaccid paralysis due to its action on peripheral cholinergic nerves. Paralysis typically presents 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include respiratory support and passive immunization with antibodies which must be administered before symptoms occur, which leaves little time post-exposure for effective treatment.

In the context of oral and nasal formulations, we are developing a multivalent vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Typically, vaccines given by mucosal routes are not immunogenic because they do not attach to immune inductive sites. In the case of the combination BT-VACCTM both the A and the B antigens were capable of attaching to cells in the mucosal epithelium and inducing an immune response with similar magnitude to the injected vaccine. Our preclinical data suggests that a bivalent formulation of serotypes A and B is completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in animal models. The animals were given a small quantity of the bivalent combination vaccine containing each of the type A and type B antigens (10 micrograms) three times a day at two week intervals. All of the animals developed equivalent immune responses to A and B types in the serum. Importantly, they were then protected against exposure to each of the native toxin molecules given at 1000 fold the dose that causes lethality. The immune responses were also comparable to the same vaccines when given by intramuscular injection.

In September 2006, we were awarded a NIAID Phase 1 SBIR grant totaling approximately $500,000 to conduct further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. The grant funding has supported further work in characterizing antigen formulations that induce protective immunity to the three most common botulinum toxin types that may be encountered naturally or in the form of a bioweapon. This work will continue the research conducted by Dr. Lance Simpson and colleagues who originally showed that recombinant non-toxic segments of the botulinum toxin can be given by the oral as well as the intranasal route to induce a strong protective immune response in animals. This observation forms the basis for development of an oral or intranasal vaccine for botulinum toxin that can be used in humans. Currently, the recombinant vaccines under development are given by intramuscular injections. The alternate route provides a self administration option, which will bypass the requirement for needles and personnel to administer the vaccine.

In July 2007, we announced that the first results from testing of a multivalent form of BT-VACCTM have been published in the journal Infection and Immunity (Ravichandran et al., 2007, Infection and Immunity, v. 75, p. 3043). These results are the first that describe the protective immunity elicited by a multivalent vaccine that is active by the mucosal route. The vaccine consists of a combination of three non-toxic subunits of botulinum toxin that induced protection against the corresponding versions of the natural toxins. The results published in Infection and Immunity show that non-toxic subunits (protein components of the natural toxin) of three of the serotypes of botulinum toxin that cause almost all instances of human disease, namely serotypes A, B, and E, can be combined and delivered via nasal administration. The combination vaccine induced antibodies in the serum of mice and protected against subsequent exposure to high doses of a combination of the natural A, B, and E serotype neurotoxins. Further, the combination vaccine can induce protection when given mucosally as a booster to animals that have been given a primary vaccine injection.

Research and Development

We have conducted a series of studies in animals that have demonstrated that the key immunogenic antigen derived from botulinum toxin can be given to animals orally and elicit a protective immune response. This has been shown with a single serotype of botulinum toxin and recently the observation has been expanded to a prototype mixture of three antigens given to animals by intranasal immunization. We have used our own capital to invest in the demonstration of product feasibility since the inception of this project in 2003, but now are using grant funding to advance further product development. We received a Phase 1 $0.5 Million SBIR grant from the NIH for project funding during 2007, and anticipate being able to obtain additional SBIR funding in 2008.

Cost and Development analysis for BT-VACC™

The costs that we have incurred to develop BT-VACC™ from 2002 were approximately $2,100,000. Research and development costs for BT-VACC™ totaled $360,997 in 2007 of which $45,915 were reimbursed under this grant and $130,381 in 2006.

3. Strategy for development of BioDefense products

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

D. Summary of Our Products in Development

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

BioTherapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of Acute GI GVHD	Phase 3 confirmatory trial to be initiated in 2008. MAA filed and under review
orBec®	Prevention of Acute GVHD	Phase 2 trial enrolling
orBec®	Treatment of Chronic GI GVHD	Phase 2 to be initiated in 2008
Oral BDP	Radiation Enteritis and Radiation Exposure	Phase 2 to be initiated in 2008
LPMTM – Leuprolide	Endometriosis and Prostate Cancer	Phase 1 to be initiated in 2008
OraprineTM	Oral lesions resulting from Graft-versus-Host Disease	Phase 1/2 ro be initiated in 2009
LPETM and PLPTM Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

Biodefense Products

Select Agent	Currently Available Countermeasure	DOR Biodefense Product
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricin Vaccine Phase 1 Clinical Trial Successfully Completed
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral/Nasal Botulinum Vaccine

E. The Drug Approval Process

1. General

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

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

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

Clinical trials are normally done in three Phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 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 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship 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 4, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice 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 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing 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 will likely be required to be submitted to the FDA or foreign regulatory authority.

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

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

2. Marketing Strategies

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec® and sale or merger of all of our assets. We may seek a marketing partner in the U.S. and abroad in anticipation of the eventual commercialization of orBec®. We are actively seeking a partner for orBec® for territories both inside and outside North America. We are actively seeking a partner for the development of other potential indications of orBec® as well as for our OraprineTM, LPMTM – Leuprolide, LPETM and PLPTM systems for delivery of water-insoluble drugs. If and when approved, we also are considering a strategy of a commercial launch of orBec® by ourselves in the U.S.

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of our biodefense vaccine products. We may market our biodefense vaccine products directly to government agencies. We believe that both military and civilian health authorities of the United States and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

3. Competition

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

A. Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Dynavax, Emergent Biosolutions (formerly Bioport Corporation), VaxGen, Inc., Chimerix, Inc., Human Genome Sciences, Inc., Coley Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmathene, SIGA Pharmaceuticals 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, Avecia Biotechnology, Inc. has received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen received an approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of Anthrax vaccine. This contract was rescinded in January 2007 by the HHS because of the inability of Vaxgen to enter into Phase 2 clinical trials according to contract timelines. Several companies have received development grants from NIH for biodefense products. For example, Coley Pharmaceuticals, Inc. has received a $6 million Department of Defense grant to develop vaccine enhancement technology. Dynport Vaccine Company, LLC, a prime contractor with the DOD, currently has a $200 million contract to develop vaccines for the U.S. Military, including a multivalent botulinum toxin vaccine. Although we have received significant grant funding to date for product development, we have not yet been obtained contract awards for government procurement of products.

B. orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat GVHD by suppressing the immune system through various mechanisms. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat graft-vs.-host disease.

Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat graft-vs.-host disease. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant related therapeutics. We face potential competition from Osiris Therapeutics if their product Prochymal for the treatment of GI GVHD is successful in ongoing Phase 3 clinical trials and reaches market. Kiadis Pharma is also developing products for the treatment of GVHD. In addition, there are investigator-sponsored clinical trials exploring the use of approved drugs such as Enbrel®, which has been approved by the FDA for the treatment of rheumatoid arthritis, in the treatment of GVHD. We believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make orBec® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product RemicadeTM for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®. Entocort is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In Italy, Chiesi Pharmaceuticals markets an oral formulation of beclomethasone dipropionate, the active ingredient of orBec® for ulcerative colitis and may seek marketing approval for their product in countries other than Italy including the United States. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis called Colazal®.

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

4. Patents and Other Proprietary Rights

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

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

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

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.

5. orBec® License Agreement

In October 1998, our wholly-owned subsidiary, Enteron Pharmaceuticals, Inc. (Enteron), entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, M.D., including the right to grant sublicenses, for the rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDonald receives $40,000 per annum as a consultant.

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®.

6. 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 (UTSW) for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine for initial license fees of $200,000 of our common stock and $100,000 in cash. Subsequently, in October 2004, we negotiated the remaining oral rights to the ricin vaccine for additional license fees of $150,000 in cash. Our license obligates us to pay $50,000 in annual license fees.

We have sponsored research agreements with UTSW funded by two NIH grants. On December 7, 2006, we announced that the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance of patent claims based on U.S. Patent Application #09/698,551 entitled "Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin." This patent includes methods of use and composition claims for RiVax™.

7. Botulinum Toxin Vaccine Intellectual Property

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

8. Employees

As of December 31, 2007, we had six full-time employees, three of whom are Ph.Ds.

9. Research and Development Spending

We spent approximately $3,100,000 and $4,800,000 in the years ended December 31, 2007 and 2006, respectively, on research and development.

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Cautionary Note Regarding Forward-Looking Statements

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

Risk Factors

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Below are the significant risks and uncertainties of which we are aware. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this Annual Report, including our financial statements and the related notes.

Risks Related to our Industry

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

We have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2007, we had $2,220,128 in cash available. On January 3, 2007, we completed the sale of 4,065,041 shares of our common stock to Sigma-Tau for a purchase price of $1,000,000. On February 9, 2007, we completed the sale of an aggregate of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for an aggregate purchase price of $5,490,000. In addition, during the twelve months ended December 31, 2007, we had warrant and stock option exercises of approximately $2,200,000. Based on our projected budgetary needs over the next 12 months, we expect to be able to maintain the current level of our operations through the first quarter of 2009. However we may not have sufficient funds to finance a new Phase 3 clinical trial of orBec® for the treatment of GI GVHD without being able to fully utilize the Fusion Capital facility.

We have sufficient funds through our existing, biodefense grant facilities National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”) to finance our biodefense projects. On September 29, 2006, we announced that we had received approximately $5,300,000 in grants for the development of our biodefense programs. We estimate that the overhead revenue contribution from our existing NIH biodefense grants will generate an additional $850,000 over the next four quarters.

All of our products are currently in preclinical studies or clinical trials, and we have not yet generated any revenues from sales or licensing of them. Through December 31, 2007, we had expended approximately $20,500,000 developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $7 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our lead product candidate, or another one of our product candidates, we will require additional funding though our existing Fusion Capital facility or another financing source to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations

If the price of our stock is less than $0.10 per share, we cannot utilize the Fusion Capital facility, and, in such event, 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 adequate financing is not obtained through our facility with Fusion Capital, we will require additional financing to sustain our operations and without it we may not be able to continue operations at present levels

At December 31, 2007, we had working capital of $1,243,638, and a net loss of $6,164,643. Based on the our current rate of cash outflows, cash in the bank, and expected proceeds from the Fusion Capital common stock purchase agreement, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the fourth quarter of 2009. If we are not able to access the Fusion Capital facility, we believe our cash will only be sufficient to sustain reduced operations into the first quarter of 2009.

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.5 million over approximately a 25-month period. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000.

We only have the right to receive $80,000 per every three trading days under the agreement with Fusion Capital unless our stock price equals or exceeds $0.15, in which case the amount may be increased under certain conditions as the price of our common stock increases. We cannot require Fusion Capital to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.10. We have initially registered 22,777,778 shares for sale by Fusion Capital (excluding the 2,550,000 commitment fee shares). The selling price of our common stock to Fusion Capital will have to average at least $0.37 per share for us to receive the maximum proceeds of $8.5 million without registering additional shares of common stock. Assuming a purchase price of $0.22 per share (the closing sale price of the common stock on March 3, 2008), proceeds to us would only be $4,900,000, which includes the $500,000 already received, unless we choose to register more than 22,777,778 shares (excluding the 2,550,000 commitment fee shares), which we have the right to do. We have the right under the common stock purchase agreement to issue more than 22,777,778 (excluding the 2,550,000 commitment fee shares) shares to Fusion Capital. In the event we elect to issue more than the 22,777,778 (excluding the 2,550,000 commitment fee shares) shares, we will be required to file a new registration statement and have it declared effective by the SEC, although we currently have no present intention to register additional shares.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences require us to reduce our present level of operations and such a reduction could have a material adverse effect on our business, operating results, financial condition and prospects.

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

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

- we will not be able to maintain our current research and development schedules;
- we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;
- we will encounter problems in clinical trials; or
- the technology or product will be found to be ineffective or unsafe.

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

- it is uneconomical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

We received a not approvable letter from the FDA for our lead product candidate orBec®.

Our business is subject to very stringent United States, federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

On October 18, 2007, we received a not approvable letter from the FDA for our lead product candidate, orBec®, for the treatment of gastrointestinal GI GVHD. The letter stated that the FDA requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. The FDA also has requested nonclinical and chemistry, manufacturing & controls information as part of the not approvable letter. On October 19, 2007, we requested an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the

confirmatory trial under the Agency's Special Protocol Assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008.

Although we intend to obtain FDA approval for orBec®, there can be no assurances that the FDA will ever approve orBec® for market.

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

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 not be able 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.

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

There may be unforeseen challenges in developing our biodefense products.

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

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

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

The manufacture of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.

We do not have experience in marketing or selling pharmaceutical products. We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize orBec® or any other potential product in the United States or elsewhere.

Our products, if approved, may not be commercially viable due to change in health care practice 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, and George B. McDonald M.D. for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

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

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

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

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or

other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

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

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

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

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

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

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

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

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

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

We have only six employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Dr. Christopher J. Schaber, our Chief Executive Officer, was hired in August 2006; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was a member of our Board of Directors for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. In May 2007, Steve H. Kanzer resigned from the Board of Directors. In June 2007, Cyrille F. Buhrman was elected to the Board of Directors. We will not be successful if this management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Risks Related to our Common Stock

Our stock price is highly volatile.

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

- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our quarterly operating results and performance;
- announcements by us or others of results of pre-clinical testing and clinical trials;
- developments or disputes concerning patents or other proprietary rights;
- acquisitions;
- litigation and government proceedings;
- adverse legislation;
- changes in government regulations;
- economic and other external factors; and
- general market conditions.

In addition, potential dilutive effects of future sales of shares of common stock by shareholders and by the Company, including Fusion Capital and subsequent sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

Our stock price has fluctuated between January 1, 2004 through December 31, 2007, the per share price of our common stock ranged between a high of $1.58 per share to a low of $0.15 per share. As of March 24, 2008, our

common stock traded at $0.175. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock trades on the over the counter bulletin board.

On April 18, 2006, our stock was delisted from the American Stock Exchange ("AMEX") and began trading on the Over-the-Counter Bulletin Board (the "OTCBB") securities market on April 18, 2006 under the ticker symbol DORB. The OTCBB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies. On the OTCBB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCBB securities include national, regional, and foreign equity issues. Companies traded OTCBB must be current in their reports filed with the SEC and other regulatory authorities.

Our stock was delisted from the AMEX because we did not maintain shareholder equity above $6,000,000, as required under the maintenance requirement for continued listing.

If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Our common stock is 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, our common stock could be priced at a lower price and our stockholders could find it more difficult to sell their shares.

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Shareholders may suffer substantial dilution.

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

- warrants to purchase a total of approximately 30,900,000 shares of our common stock at a current weighted average exercise price of approximately $0.67;
- anti-dilution rights associated with a small portion of the above warrants which can permit purchase of additional shares and/or lower exercise prices under certain circumstances; and
- options to purchase approximately 10,250,000 shares of our common stock of a current weighted average exercise price of approximately $0.44.

During 2008, approximately 10,000,000 of the Company's existing warrants will be reaching expiration. By April 2009, approximately 20,000,000 of the Company's existing warrants will be reaching expiration.

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

Shareholders are also subject to the risk of substantial dilution to their interests as a result of our issuance of shares under the common stock purchase agreement with Fusion Capital. Under the agreement, we have the right, but not the obligation, under certain conditions, to sell shares of common stock to Fusion Capital in an aggregate amount of $8.5 million from time to time over a 25 month period. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale.

We already have sold 2,777,778 shares of common stock to Fusion Capital (together with a warrant to purchase 1,388,889 shares of our common stock) under the agreement for total proceeds of $500,000. In addition to the shares already sold to Fusion Capital, we have filed a registration statement with respect to 20 million shares that may be sold to Fusion Capital. We may ultimately sell all, some or none of the 20 million shares of common stock. If such 20 million shares were issued and outstanding as of March 3, 2008, the 20 million shares would have represented approximately 20% of the total outstanding common stock.

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

We cannot begin sales of our common stock to Fusion Capital until the effectiveness of the recently filed registration statement and the common stock purchase agreement may be terminated in the event of a default under the agreement. In addition, we may not require Fusion Capital to purchase any shares of our common stock if the purchase price is less than $0.10 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. See "Fusion Transaction."

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by fusion capital could cause the price of our common stock to decline.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital under the recently filed registration statement is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 25,327,778 shares recently filed for registration are expected to be freely tradable. It is anticipated that those shares will be sold over a period of up to 25 months from the

date on the prospectus. Depending upon market liquidity at the time, a sale of shares under the recently filed registration statement at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the 20 million shares of common stock not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

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

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

Fusion Capital's purchase and sale into the market of our common stock could cause our common stock price to decline due to the additional shares available in the market, particularly in light of the relatively thin trading volume of our common stock. The market price of our common stock could decline given our minimal average trading volume compared to the number of shares potentially issuable to Fusion Capital, and the voting power and value of your investment would be subject to continual dilution if Fusion Capital purchases the shares and resells those shares into the market, although there is no obligation for Fusion Capital to sell such shares. Any adverse affect on the market price of our common stock would increase the number of shares issuable to Fusion Capital which would increase the potential dilution of your investment.

Item 2. Description of Property

We currently lease approximately 3,000 square feet of office space at 850 Bear Tavern Road, Suite 202, Ewing, New Jersey 08628. The office space currently serves as our corporate headquarters. We pay rent of approximately $3,621 per month and CAM charges of approximately $2,200 on a one-year lease, which was entered into on October 1, 2007 and expires on September 30, 2008. We believe that our current leased facilities are sufficient to meet our current needs.

Item 3. Legal Proceedings

For the past several years Edwards Angell Palmer and Dodge LLP has been retained as our outside legal counsel.

From time-to-time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

On October 28, 2005, we entered into a letter of intent to acquire Gastrotech Pharma A/S (Gastrotech), a private, Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. On January 26, 2006, we advised Gastrotech that we were not renewing our letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1,000,000 breakup fee in the event either party notified the other of its intention not to proceed with the transaction. The attorney representing Gastrotech has advised us that if we are not willing to comply with the terms in the letter of intent, we will be in material breach of our obligations under the letter of intent and will be obligated to pay Gastrotech a break-up fee of $1,000,000. As of the date of this report, no claim or complaint has been filed by Gastrotech as to the obligation to pay a break-up fee of $1,000,000. Our position is that we do not owe Gastrotech any break-up fee pursuant to not renewing the letter of intent to acquire Gastrotech.

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

None.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters.

Our common stock is traded on the Over The Counter Bulletin Board (“OTCBB”) under the symbol "DORB." The table below sets forth the high and low sales prices, as provided by the American Stock Exchange and as reported on the Website of the OTCBB, for the period from January 1, 2006 through December 31, 2007. Until April 18, 2006, our common stock was listed on the American Stock Exchange. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

Period	Price Range	
	High	Low
Fiscal Year Ended December 31, 2006:		
First Quarter	$0.69	$0.26
Second Quarter	$0.40	$0.23
Third Quarter	$0.33	$0.20
Fourth Quarter	$0.30	$0.21
Fiscal Year Ended December 31, 2007:		
First Quarter	$0.71	$0.23
Second Quarter	$0.95	$0.20
Third Quarter	$0.40	$0.26
Fourth Quarter	$0.61	$0.15

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of March 24, 2008, the last reported price of our common stock was $0.175 per share. The OTCBB price quoted reflects inter-dealer prices, without retail mark-up, mark down or commission, and may not represent actual transactions. We have approximately 1,071 registered holders of record.

Dividend Policy

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

Item 6. Management's Discussion and Analysis or Plan of Operation.

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this Annual Report which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Item1. Description of Business-Risk Factors" in this Annual Report. See "Item1 .Description of Business-Cautionary Note Regarding Forward-Looking Statements."

Business Overview and Strategy

We are a late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. On September 21, 2006, we filed a new drug application ("NDA") for our lead product, orBec® (oral beclomethasone dipropionate), with the U.S. Food and Drug Administration (the "FDA") for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"). On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicines Evaluation Agency ("EMEA") for orBec®, which is currently under review. We anticipate receiving the EMEA's official opinion to our MAA in the first half of 2008.

On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting; (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's Special Protocol Assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008.

We maintain two active segments: BioTherapeutics and BioDefense. Our business strategy is to: (a) work with the FDA on the design of new clinical trials in GI GVHD; (b) seek a development and marketing partner for orBec® for territories both inside and outside of the US; (c) prepare for the potential marketing approval of orBec® by the EMEA; (d) conduct a prophylactic use clinical trial of orBec® for the prevention of GI GVHD; (e) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis and Crohn's disease; (f) reinitiate development including manufacturing of our other biotherapeutics products namely LPMTM-Leuprolide, and OraprineTM; (g) secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts, and procurements; (h) explore acquisition strategies under which the Company may be acquired by another company with oncologic or gastrointestinal symmetry; (i) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area; and (j) acquire or in-license new clinical-stage compounds for development.

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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.

Intangible Assets

One of the most significant estimates or judgments 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 and defense of patents.

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.

We capitalize and amortize intangibles over a period of 11 to 16 years. We capitalize payments made to legal firms that are engaged in filing and protecting our rights to our intellectual property and rights for our current products in both the domestic and international markets.

We capitalize intangible assets that have alternative future uses. This is common practice in the pharmaceutical development industry. Of the intangible asset balance as of December 31, 2006 and December 31, 2007, $1,025,000 and $425,000, respectively, are for up-front license costs. We purchased the RiVaxTM vaccine license from the University of Texas Southwestern Medical Center for $425,000. We capitalize license costs because they have alternative future use as referred to in paragraph 11 c. of SFAS No.2. We believe that both of these intangible assets purchased have alternative future uses.

We capitalize legal costs associated with the protection and maintenance of our patents. For a development stage company with drug and vaccine products in an often lengthy basic and clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. We capitalize intangible assets alternative future use as referred to in SFAS No.142 and in paragraph 11 c. of SFAS No. 2.

We capitalized $356,192 and $206,004 in patent related costs during the year ended December 31, 2007 and December 31, 2006, respectively. These amounts are represented in the cash flow statements, in the section for investing activities presented in the financial statements included in this report. On the balance sheet as of December 31, 2007 and December 31, 2006, these amounts are presented on the line intangible assets, net in the amount of $1,320,787 and $1,073,239, respectively.

Research and Development Costs

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

Revenue Recognition

All of our revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides partial funding of our overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

Material Changes in Results of Operations

We are a research and development company. The 2007 revenues and associated expenses were from NIH Grants awarded in September 2004 and September 2006. The NIH grants are associated with our ricin and botulinum vaccines. In addition, we were awarded a one year FDA Orphan Products grant on September 23, 2005 for "Oral BDP for the Treatment of GI GVHD."

For the year ended December 31, 2007, we had grant revenues of $1,258,017 as compared to $2,313,020 in the twelve months ended December 31, 2006, a decrease of $1,055,003, or 46%. In 2006 compared to 2007, our progress on the grant had exceeded the original schedule, which accelerated the milestone revenues that were recorded in the first quarter of 2006. We also incurred expenses correlated to the revenue in 2007 and 2006 of $943,385 and $1,965,074, respectively, a decrease of $1,021,689, or 52%. These costs relate to payments made to subcontractors and universities in connection with the grants.

The gross profit for the twelve months ended December 31, 2007 was $314,632 as compared to $347,946 in the twelve months ended December 31, 2006, a decrease of $33,314, or 10%. This was due to the decreased grant revenues in the first quarter ended 2007 that were eligible for the F&A rate as well as the expected decrease in the final F&A rate.

Research and development spending decreased $538,549, or 15%, to $3,099,944, for the twelve months ended December 31, 2007 as compared to $3,638,493 for the corresponding period ended December 31, 2006. In the third quarter of 2007, a majority of expenses were related to preparation of FDA and European regulatory matters. During the fourth quarter of 2007 our research and development expenses were greatly reduced as a result of the end of FDA's review of our NDA for orBec®.

In-process research and development expenditures were $0 for the twelve months ended December 31, 2007, a decrease of 100% as compared to $981,819 for the same period ended December 31, 2006. This decrease was due to the purchase acquisition in 2006 of all of the outstanding common stock of Enteron that the Company did not already own.

Impairment expense for intangibles was $0 for the twelve months ended December 31, 2007, a decrease of 100% as compared to $816,300 for the same period ended December 31, 2006. This was due to the impairment of the Southern Research Institute/Brookwood Pharmaceuticals license of microsphere technology.

Stock based compensation expenses for research and development increased $10,733, or 5%, to $230,668 for the twelve months ended December 31, 2007, as compared to $219,895 for the corresponding period ended December 31, 2006.

Stock based compensation expenses for general and administrative increased $109,486, or 32%, to $446,773 for the twelve months ended December 31, 2007, as compared to $337,287 for the corresponding period ended December 31, 2006.

General and administrative expenses increased $310,670, or 12%, to $2,864,370 for the twelve months ended December 31, 2007, as compared to $2,553,700 for the corresponding period ended December 31, 2006. The increase was primarily due to the dilution expense taken for stock issued to investors from the April 2006 PIPE in the amount of $308,743. In addition, we had expenses for public and investor relations which increased by approximately $125,000.

Interest income for the twelve months ended December 31, 2007 was $164,847 as compared to $41,510 for the twelve months ended December 31, 2006, representing an increase of $123,337 or 297%. This increase is due to a higher

cash balance in 2007 as compared to 2006.

Interest expense for the twelve months ended December 31, 2007 was $1,020 as compared to $5,308 for the twelve months ended December 31, 2006, a decrease of $4,288 or 81%. This decrease was the result of lower balances that were short-term financed for insurance premiums due and therefore less interest was accrued and paid.

For the twelve months ended December 31, 2007, we had a net loss of $6,164,643 as compared to a $8,163,346 net loss for the twelve months ended December 31, 2006, a decrease of $1,998,703, or 24%. This decrease in the net loss is primarily attributed to higher costs in 2006 for: regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®; the in-process research and development expense of $981,819 for acquiring all of the outstanding common stock of Enteron that the Company did not already own, the impairment expense for intangibles of $816,300, and the dilution expense taken for stock issued to investors from the April 2006 PIPE in the amount of $308,743.

Financial Condition

Cash and Working Capital

As of December 31, 2007, we had cash of $2,220,128 as compared to $119,636 as of December 31, 2006. As of March 24, 2008 we had cash of approximately $2,000,000. As of December 31, 2007, we had working capital of $1,243,638 as compared to negative working capital of $2,211,387 as of December 31, 2006, representing an increase of $3,455,025. For the twelve months ended December 31, 2007, our cash used in operating activities was approximately $6,000,000, compared to $4,100,000 for the corresponding period ended December 31, 2006.

Based on the our current rate of cash outflows, cash in the bank, and expected proceeds from the Fusion Capital common stock purchase agreement, we believe that our cash will be sufficient to meet its anticipated cash needs for working capital and capital expenditures through the fourth quarter of 2009. If we are not able to access the Fusion Capital facility, we believe our cash will only be sufficient to sustain reduced operations into the first quarter of 2009.

We believe that utilizing this facility will allow us to begin the phase 3 clinical trial of for orBec®. It is possible that we will seek additional capital in the private and/or public equity markets to expand our operations, to respond to competitive pressures, to develop new products and services and to support new strategic partnerships. We may obtain capital pursuant to one or more corporate partnerships relating to orBec®. If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms or at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

The extent we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full $8.5 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

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Expenditures

Under existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our expenditures for the next 12 months to be approximately $3,500,000, not inclusive of BioDefense programs, nor programs covered under existing NIH or orphan grants, and not including a new Phase 3 clinical trial for orBec® for the treatment of GI GVHD. We anticipate grant revenues in the next 12 months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $2,900,000 with $950,000 contributing towards our overhead expenses.

The table below details our costs for the twelve months ended December 31, 2007 and December 31, 2006 by program.

	2007	2006
Program - Research & Development Expenses		
orBec®	$ 2,288,615	$ 3,060,778
RiVax™	452,894	274,635
BT-VACC™	315,082	290,405
Oraprine™	5,100	6,996
LPMTM-Leuprolide	38,254	5,679
Research & Development Expense	$ 3,099,945	$ 3,638,493
Program - Reimbursed under Grants		
orBec®	$ -	$ -
RiVax™	897,470	1,961,074
BT-VACC™	45,915	4,000
Oraprine™	-	-
LPMTM-Leuprolide	-	-
Reimbursed under Grant	$ 943,385	$ 1,965,074
TOTAL	$ 4,043,330	$ 5,603,567

Debt

We had no debt at December 31, 2007 or at December 31, 2006.

Leases

The following summarizes our contractual obligations at December 31, 2007, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	Year 2008	Year 2009	Year 2010
Non-cancelable obligation (1)	$ 54,000	$ -	$ -
TOTALS	$ 54,000	$ -	$ -

(1) On October 1, 2007, we signed a one year lease to occupy office space in Ewing, New Jersey.

Equity Transactions

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.5 million over approximately a 25-month period. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. If our stock price exceeds $0.15, then the amount required to purchase may be increased under certain conditions as the price of our common stock increases. We cannot require Fusion Capital to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.10.

On February 9, 2007, we completed the sale of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for a purchase price of $5,490,000. These shares have been registered.

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction's dilutive nature, all investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders who still held shares of the Company's common stock from that placement were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. These investors, nor any others for that matter, hold any further anti-dilution rights. Because no agreement was reached by March 1, 2007, we were obligated to return the $2 million to Sigma-Tau by April 30, 2007. On June 1, 2007, we returned the $2 million to Sigma Tau.

On April 10, 2006, we completed the sale of 13,099,964 shares of our common stock to institutional and other accredited investors, including members of our management team, for a purchase price of $3,630,000. The investors also received warrants to purchase an aggregate of 13,099,964 shares of our common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. We filed a registration statement with the Securities and Exchange Commission covering the shares of common stock issued and issuable pursuant to the exercise of the warrants, and it was declared effective on May 25, 2006.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital. The Fusion Capital facility allowed it to purchase on each trading day $20,000 of our common stock up to an aggregate of $6 million over approximately a 15-month period. As part of that agreement we issued Fusion Capital 512,500 shares of common stock as a commitment fee. During 2006, Fusion purchased 329,540 common shares for $124,968.

In February 2005, we increased our cash position by the issuance and sale of 8,396,100 shares of our common stock at $0.45 per share in a private placement to institutional investors. These investors also received warrants to purchase 6,297,075 shares of our common stock at an exercise price of $0.505 per share. The proceeds after related expenses and closing costs were approximately $3.5 million. We do not believe these warrants required application of SFAS No. 133. We determined this based on two interpretations of SFAS No. 133. First, the warrants have no initial allocable investment (paragraph 8 of SFAS No. 133). All three classes of warrants in question were issued in connection with private placements whose participants purchased units that included upfront shares as well as a certain percentage of out-of-the-money warrants deemed to have some future benefit. Second, all three classes of warrants are "regular-way" security trades as described in paragraph 10 of SFAS No. 133. Once exercised for cash, the warrant holders are issued common stock shares within three business days as required by public exchanges.

For the February 2005 private placement, the warrants provide that if the shares are not registered and are available for sale by the effectiveness date as specified in the respective registration rights agreements, then the holders of the warrants can do a cashless exercise. Both conditions were met so the cashless feature expired. In the April 2006 private placement, warrant holders could only exercise the warrants on a cashless basis if the registration statement for the shares was not declared effective by the SEC by the first anniversary date of the closing of the transaction. The registration statement was declared effective in May 2006.

All classes of warrants are classified as equity instruments under EITF No. 00-19 because they bear:

1. Physical settlement method - That is we will issue shares for cash, and
2. The contracts are freestanding – As described in paragraphs 1, 2, 8, 38 and 39 of EITF No. 00-19.

If these warrants were hedging relationships as described in SFAS No. 133, paragraph 21, the warrants are not required to be accounted for as an asset or a liability because of our call option. See EITF 00-19, paragraph 7. Also, specifically for the April 2006 Private Placement, the warrants issued would require that we deliver shares. This classification requires it to be classified as equity. See (EITF 00-19, paragraph 9).

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the fiscal year ended December 31, 2006 or the quarter ended September 30, 2007.

Item 7. Financial Statements.

See Item 13(1) of this Annual Report.

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

None.

Item 8A. Controls and Procedures

Disclosure Controls and Procedures

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

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2007, our internal control over financial reporting is effective based on these criteria.

This report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

Our management also has indicated that there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their evaluation, and there were no significant deficiencies or material weaknesses.

Item 8B. Other Information

None.

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PART III

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

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

Name	Age	Position
James S. Kuo, M.D., M.B.A.	43	Chairman of the Board
Cyrille F. Buhrman	35	Director
Christopher J. Schaber, Ph.D.	41	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	43	Chief Financial Officer, and Director
James Clavijo, C.P.A., M.A.	41	Controller, Treasurer, and Corporate Secretary

James S. Kuo, M.D., M.B.A., has been a director since 2004 and currently serves as the non-executive Chairman of the Board. He has served as Chairman of the Board of Directors of Duska Therapeutics, Inc., a public biopharmaceutical company, since June 2007 and has been Chief Executive Officer since September 2007. From 2006 to September 2007, he served as Chairman and Chief Executive Officer of Cysteine Pharma, Inc. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc., a private venture-backed, microfluidics company. Prior to that time, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories, Inc., a public specialty pharmaceutical company developing respiratory therapies, where he raised over $22 million in initial private funding and took the company public. He further has been a founder and a Board Director of Monarch Labs, LLC, a private medical device company. Dr. Kuo is the former Managing Director of Venture Analysis for HealthCare Ventures, LLC, which managed $378 million in venture funds. He has also been a senior licensing and business development executive at Pfizer, Inc., where he was directly responsible for cardiovascular licensing and development. After studying molecular biology and receiving his B.A. at Haverford College, Dr. Kuo simultaneously received his M.D. from The University of Pennsylvania School of Medicine and his MBA from The Wharton School of Business at the University of Pennsylvania. Dr. Kuo is also a director of Pipex Pharmaceuticals, Inc., a public company.

Cyrille F. Buhrman has been a director since June 2007. Mr. Buhrman is Chairman and President of the Pacific Healthcare Group of Companies, a full-service marketing, sales, distribution and regulatory affairs company based in Thailand where he has served for approximately ten years. Mr. Buhrman is also a Director of International Pharmaceuticals Ltd., a company focused on marketing niche pharmaceuticals and other medical products in Thailand, Vision Care (Thailand) Co., Ltd., and Canyon Pharmaceuticals, Inc., a private biotechnology company focused on the commercialization of therapeutics to prevent and treat thrombosis and related conditions. Mr. Buhrman is owner of Markle Holdings Ltd., an investment fund specializing in biotech and pharmaceutical investments. Mr. Buhrman is also one of our largest shareholders.

Christopher J. Schaber, Ph.D., has been our President and Chief Executive Officer and a director since August 2006. Prior to joining us, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, preclinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising in excess of $150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, his M.S. in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. in Pharmaceutical Sciences from The Union Graduate School.

Evan Myrianthopoulos has been a director since 2002 and is currently our Chief Financial Officer, after joining us in November of 2004 as President and Acting Chief Executive Officer. From November 2001 to November 2004, he was President and founder of CVL Advisors Group Inc., a financial consulting firm specializing in the biotechnology sector. Prior to founding CVL Advisors Group, Inc., Mr. Myrianthopoulos was a co-founder of Discovery Laboratories, Inc. During his tenure at Discovery Laboratories, Inc. from June 1996 to November 2001, Mr. Myrianthopoulos held the positions of Chief Financial Officer and Vice President of Finance, where he was responsible for raising approximately $55 million in four private placements. He also helped negotiate and manage Discovery Laboratories, Inc.'s mergers with Ansan Pharmaceuticals and Acute Therapeutics, Inc. Prior to co-founding Discovery Laboratories, Inc., Mr. Myrianthopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm. Prior to joining Paramount Capital Investments, LLC, Mr. Myrianthopoulos was a managing partner at a hedge fund and also held senior positions in the treasury department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr. Myrianthopoulos holds a B.S. in Economics and Psychology from Emory University.

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

To our knowledge, based solely on review of these filings and written representations from the certain reporting persons, we believe that during the fiscal year ended December 31, 2007, our officers, directors and significant

stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act, except for a late Form 4 (one filing) for Mr. Kanzer and a late Form 4 (one filing) for Dr. Kuo.

Code of Ethics

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

Audit Committee Financial Expert

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

Item 10. Executive Compensation

Summary Compensation

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2006 and 2007 to the persons who served as our Chief Executive Officers, and each of the two other most highly compensated executive officers during 2007 (collectively, the "Named Executive Officers").

Summary Compensation Table

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber (1)	CEO & President	2006	$104,700	$ 33,333	$185,403	$16,895	$340,331
		2007	$300,000	$100,000	$155,409	$28,798	$584,207
Evan Myrianthopoulos (2)	CFO	2006	$195,724	$ 55,000	$103,064	$49,257	$398,045
		2007	$200,000	$ 50,000	$146,938	$27,786	$324,724
James Clavijo (3)	Controller, Treasurer & Secretary	2006	$144,999	$ 40,000	$ 42,836	$ -	$222,835
		2007	$155,000	$ 35,000	$ 53,115	$ -	$243,115

(1) Dr. Schaber deferred payment of his 2007 annual bonus of $100,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2007 includes $2,301 for transportation costs, $7,263 for travel expenses and $19,234 for lodging costs. Other Compensation for 2006 includes $1,430 for transportation costs, $6,458 for travel expenses and $9,007 for lodging costs.

(2) Mr. Myrianthopoulos deferred payment of his 2007 annual bonus of $50,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2007 includes $2,895 for transportation costs, $6,787 for travel expenses and $18,104 for lodging costs. Other Compensation for 2006 includes $4,088 for transportation costs, $12,485 for travel expenses and $32,684 for lodging costs.

(3) Mr. Clavijo deferred payment of his 2007 annual bonus of $35,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R.

Potential Issuance of Shares

On February 28, 2007, our Board of Directors approved the issuance of 2,700,000 shares of our common stock to certain employees and a consultant. Such shares will be issued immediately prior to the completion of a transaction, or series or combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party (an "Acquisition Event"). Of the shares of common stock to be issued upon an Acquisition Event, 1,000,000 shares will be issued to Christopher J. Schaber, a director and our Chief Executive Officer and President; 750,000 shares will be issued to Evan Myrianthopoulos, a director and our Chief Financial Officer; and 300,000 shares will be issued to James Clavijo, our Controller, Treasurer, and Corporate Secretary.

Employment and Severance Agreements

During August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, Ph. D. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. We agreed to issue him options to purchase 2,500,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependants. No unvested options shall vest beyond the termination date.

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

During May 2006, we entered into an amendment to the February 2005 employment agreement with James Clavijo. Pursuant to the amendment we agreed to pay Mr. Clavijo a base salary of $150,000 per year and a minimum annual bonus of $35,000. Additionally we agreed to issue him options to purchase 200,000 options of our common stock, with 50,000 options immediately vesting and the remainder vesting over three years. In the February 2005 employment agreement, we agreed to issue 150,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Mr. Clavijo three months severance, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. Mr. Clavijo also received 100,000 options, vesting over three years when he was hired in October 2004, as Controller, Treasurer and Corporate Secretary.

On December 27, 2007, we entered into a new three-year employment agreement with Dr. Schaber, Mr. Myrianthopoulos and Mr. Clavijo, which replaced their existing employment agreements. The primary changes to the terms of the original agreements are as follows:

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Messrs. Myrianthopoulos and Clavijo immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from the Company and/or our stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; and 300,000 common shares to Mr. Clavijo. The amended agreements include our obligation to issue such shares to the executives if such event occurs.

Dr. Schaber's monetary compensation (base salary and bonus) remained unchanged from 2006. He will be paid nine months severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the rest of their term and become the property of Dr. Schaber's immediate family.

Mr. Myrianthopoulos' monetary compensation (base salary and bonus) remained unchanged from 2006. He will be paid six months severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Myrianthopoulos' options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the rest of their term and become property of Mr. Myrianthopoulos' immediate family.

Mr. Clavijo's monetary compensation (base salary and bonus) remained unchanged from 2006. He will be paid six months severance (subject to set off) upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Clavijo's options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the rest of their term and become property of Mr. Clavijo's immediate family.

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Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers during the fiscal year ended December 31, 2007. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber(1)	1,527,783	972,217	972,217	$0.27	8/28/2016
	281,250	618,750	618,750	$0.47	8/29/2017
Evan Myrianthopoulos	150,000	-	-	$0.35	11/14/2012
	50,000	-	-	$0.90	9/15/2013
	50,000	-	-	$0.58	6/11/2014
	150,000	-	-	$0.47	11/10/2014
	500,000	-	-	$0.49	12/13/2014
	275,000	125,000	125,000	$0.35	5/10/2016
	171,875	378,125	378,125	$0.47	8/29/2017
James Clavijo	100,000	-	-	$0.45	10/22/2014
	141,663	8,337	8,337	$0.45	2/22/2015
	125,000	75,000	75,000	$0.33	5/10/2016
	93,750	206,250	206,250	$0.47	8/29/2017

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2007.

Director Compensation

Name	Fees Earned of Paid in Cash ($) (1)	Option Awards ($) (2)	Total ($)
Steve H. Kanzer (3)	$23,000	$14,200	$37,200
James S. Kuo	$34,000	$94,630	$128,630
Cyrille F. Buhrman	$8,000	$54,050	$62,050

(1) 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).

(2) We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors who are not full-time employees receive an initial grant of fully vested options to purchase 150,000 shares of common stock, and subsequent annual grants of fully vested options to purchase 75,000 shares of common stock after re-election to our Board of Directors. Option Awards include the value of stock option awards of vested shares of Common Stock as required by FASB No. 123R.

(3) Mr. Kanzer resigned from our Board of Directors on May 28, 2007.

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, 2008 of (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.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Cyrille F. Buhrman (1)	5,125,020	5.2%
Christopher J. Schaber (2)	2,453,189	2.4%
Evan Myrianthopoulos (3)	1,780,625	1.7%
James S. Kuo (4)	630,000	*
James Clavijo (5)	619,441	*
All directors and executive officers as a group (5 persons)	10,608,275	10.1%

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* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of March 24, 2008 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 100,299,378 shares of common stock outstanding as of March 24, 2008.

(1) Includes 4,900,020 shares of common stock and options to purchase 225,000 shares of common stock within 60 days of March 24, 2008. The address of Mr. Buhrman is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(2) Includes 392,766 shares of common stock owned by Dr. Schaber and options to purchase 2,060,423 shares of common stock within 60 days of March 24, 2008. The address of Dr. Schaber is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(3) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 1,465,625 shares of common stock and warrants to purchase 90,220 shares of common stock within 60 days of

March 24, 2008. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(4) Includes options to purchase 625,000 shares of common stock and warrants to purchase 5,000 shares of common stock within 60 days of March 24, 2008. The address of Dr. Kuo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(5) Includes 88,191 shares of common stock owned by Mr. Clavijo and options to purchase 531,250 shares of common stock within 60 days of March 24, 2008. The address of Mr. Clavijo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

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Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2007, our stockholders approved an amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 10,000,000 shares, bringing the total shares reserved for issuance under the plan to 20,000,000 shares. The following table provides information, as of December 31, 2007, with respect to options outstanding under our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-Average Exercise Price Outstanding options, warrants and rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders (1)	10,349,839	$ 0.44	10,612,961
Equity compensation plans not approved by security holders	-	-	-
TOTAL	10,349,839	$0.44	10,612,961

(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Our 1995 Plan expired in 2005 and thus no securities remain available for future issuance under that plan. Under the amended 2005 equity incentive plan, we have issued 1,117,039 shares to individuals as payment for services in the amount of $321,166 as allowed in the plan.

Item 12. Certain Relationships and Related Transactions.

Related Party Transactions

Other than the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2007 in which the amount involved exceeded $120,000. For a discussion of our employment agreements and compensation paid to our directors, see “Item 10. Executive Compensation.”

Director Independence

The Board of Directors has determined that Cyrille F. Buhrman is "independent" as such term is defined by the applicable listing standards of American Stock Exchange. Our Board of Directors based this determination on our directors' employment relationships.

Item 13. Exhibits

The following financial statements and exhibits are filed as part of this Annual Report beginning on page 39:

(1) Financial Statements:

(i) Report of Independent Registered Public Accounting Firm.

(ii) Consolidated Balance Sheets as of December 31, 2007 and 2006.

(iii) Consolidated Statements of Operations for the years ended December 31, 2007 and 2006.

(iv) Consolidated Statements of Stockholders' Equity (Deficiency) for the years December 31, 2007 and 2006.

(v) Consolidated Statements of Cash Flows for the years ended December 31, 2007 and 2006.

(vi) Notes to Consolidated Financial Statements.

(2) Exhibits:

2.1 Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).

3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

3.2 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 4.2 included in our Registration Statement on Form S-8 (File No. 333-130801) filed on December 30, 2005).

3.3 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Annex A to our Proxy Statement filed December 12, 2006).

3.4 By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).

3.5 Certificate of Designations of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2007).

4.1 Form of Investor Warrant issued to each investor dated as of April 12, 2000 (incorporated by reference to Exhibit 4.4 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.2 Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000 (incorporated by reference to Exhibit 4.5 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.3 Warrant issued to Aries Fund dated as of May 19, 1997 (incorporated by reference to Exhibit 4.6 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.4 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997 (incorporated by reference to Exhibit 4.7 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.5 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(c) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.6 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(d) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.7 Warrant issued to Élan International Services, Ltd. Dated January 21, 1998 (incorporated by reference to Exhibit 4.4 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997).

4.8 Form of Warrant to be issued to CTD warrant holders (incorporated by reference to Exhibit 4.12 include in our Registration Statement on Form S-4 filed on October 2, 2001).

4.9 Form of Warrant issued to each investor in the December 2002 private placement (incorporated by reference to Exhibit 4.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2003).

4.10 Form of Warrant issued to each investor in the September 2003 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on July 18, 2003).

4.11 Form of Warrant issued to each investor in the March 2004 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on March 4, 2004).

4.12 Form of Warrant issued to each investor in the February 2005 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 3, 2005).

4.13 Form of Warrant issued to each investor in the April 2006 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on April 7, 2006).

4.14 Form of Warrant issued to finders in connection with the February 2007 private placement. (incorporated by reference to Exhibit 4.14 included in our registration statement on Form SB-2 filed on April 16, 2007).

4.15 Rights Agreement dated June 22, 2007, between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on June 22, 2007).

4.16 Form of Right Certificate (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on June 22, 2007).

4.17 Warrant dated February 14, 2008, issued to Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 4.17 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

4.18 Form of Warrant issued to each investor in the February 2008 private placement.*

10.1 Amended and Restated 1995 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

10.2 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 14, 2001).

10.3 Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001 (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.4 Termination of the Endorex Newco joint venture between the Company, Élan Corporation, Élan International Services, and Elan Pharmaceutical Investments dated December 12, 2002 (incorporated by reference to Exhibit 10.37 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.5 Option Agreement with General Alexander M. Haig Jr. (incorporated by reference to Exhibit 10.39 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.6 Separation agreement and General Release between the Company and Ralph Ellison dated July 9, 2004 (incorporated by reference to Exhibit 10.7 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.7 License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.8 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.8 License Agreement between the Company and Thomas Jefferson University (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.9 License Agreement between the Company and the University of Texas Medical Branch (incorporated by reference to Exhibit 10.10 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.10 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (incorporated by reference to Exhibit 10.43 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.11 Form of Subscription Agreement between the Company and each investor dated July 18, 2003 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on July 18, 2003).

10.12 Form of Securities Purchase Agreement between the Company and each investor dated March 4, 2004 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on March 4, 2004).

10.13 Employment agreement between the Company and Mike Sember dated December 7, 2004 (incorporated by reference to Exhibit 10.16 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.14 Employment agreement between the Company and Evan Myrianthopoulos dated December 7, 2004 (incorporated by reference to Exhibit 10.17 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.15 Employment agreement between the Company and James Clavijo dated February 18, 2005 (incorporated by reference to Exhibit 10.18 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.16 Form of Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 3, 2005).

10.17 Amendment No. 1 dated February 17, 2005 to the Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.20 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.18 Form Registration Rights agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on February 3, 2005).

10.19 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005).

10.20 Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).

10.21 Form of Securities Purchase Agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 20, 2006)

10.22 Form of Registration Rights agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on January 20, 2006).

10.23 Securities Purchase Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on April 7, 2006).

10.24 Registration Rights Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on April 7, 2006).

10.25 Employment Agreement, dated as of August 29, 2006, between Christopher J. Schaber, Ph.D., and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on August 30, 2006).

10.26 Letter of Intent dated January 3, 2007 by and between DOR BioPharma, Inc. and Sigma-Tau Pharmaceuticals, Inc (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 4, 2007).

10.27 January 17, 2007 letter from Cell Therapeutics, Inc. to DOR BioPharma, Inc (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 19, 2007).

10.28 Securities Purchase Agreement dated February 7, 2007 by and among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 12, 2007).

10.29 Registration Rights Agreement dated February 7, 2007 by among the Company and the investors named therein (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 12, 2007).

10.30 Letter from Sigma-Tau Pharmaceuticals, Inc. dated February 21, 2007 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 23, 2007).

10.31 Letter dated May 3, 2007 between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on May 4, 2007).

10.32 Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 28, 2007).

10.33 Employment Agreement dated December 27, 2007, between Evan Myrianthopoulos and the Company (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on December 28, 2007).

10.34 Employment Agreement dated December 27, 2007, between James Clavijo, CPA and the Company (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 28, 2007).

10.35 Common Stock Purchase Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC. (incorporated by reference to Exhibit 10.35 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

10.36 Registration Rights Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC. (incorporated by reference to Exhibit 10.36 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

10.37 Form of Securities Purchase agreement between the Company and each investor dated February 14, 2008.*

10.38 Form of Registration Rights agreement between the Company and each investor dated February 14, 2008.*

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. Filed therewith.*

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

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* Filed Herewith.

Item 14. Principal Accountant Fees and Services

	December 31,	
	2007	2006
Audit fees	$ 82,311	$ 112,695
Audit related fees	4,000	19,590
Tax fees	10,202	14,292
Total	$ 96,513	$ 146,577

Audit Fees

The preceding table highlights the aggregate fees billed during the years ended December 31, 2007 and 2006 by Sweeney, Gates & Co., our principal accountants in 2007 and 2006 for the audit of our financial statements for each of those years and review of our financial statements included in our Quarterly Reports on Form 10-QSB during those fiscal years.

Audit Related Fees

The aggregate fees billed for audit related fees such as registration statements and related services during the years ended December 31, 2007 and 2006 were $4,000 and $19,590, respectively.

Tax Fees

Our current principal accountants Sweeney, Gates & Co. billed us $10,202 and $14,292 for tax compliance for the year ended December 31, 2007 and 2006, respectively.

Other Fees

Our principal accountant did not bill us for any services or products other than as reported above in this Item 14 during our fiscal years ended December 31, 2007 and 2006.

Pre Approval Policies and Procedures

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

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

INDEX TO FINANCIAL STATEMENTS

DOR BIOPHARMA, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of DOR BioPharma, Inc. and subsidiaries as of December 31, 2007 and 2006 and the related consolidated statements of operations, changes in shareholders' equity (deficiency) and cash flows for the years ended December 31, 2007 and 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years ended December 31, 2007, in conformity with United States generally accepted accounting principals.

/s/ Sweeney, Gates & Co.

Fort Lauderdale, Florida
March 8, 2008

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DOR BioPharma, Inc.
Consolidated Balance Sheets
December 31,

	2007	2006
Assets		
Current assets:		
Cash	$ 2,220,128	$ 119,636
Grants receivable	97,845	89,933
Prepaid expenses	119,178	94,470
Total current assets	2,437,151	304,039
Office and laboratory equipment, net	25,941	29,692
Intangible assets, net	1,320,787	1,073,239
Total assets	$ 3,783,879	$ 1,406,970
Liabilities and shareholders' equity (deficiency)		
Current liabilities:		
Accounts payable	$ 847,610	$ 2,112,479
Accrued compensation	345,903	402,947
Total current liabilities	1,193,513	2,515,426
Shareholders' equity (deficiency):		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 94,996,547 and 68,855,794, respectively issued and outstanding	94,996	68,855
Additional paid-in capital	101,391,090	91,553,766
	)	()
Accumulated deficit	(98,895,720	92,731,077
Total shareholders' equity (deficiency)	2,590,366	(1,108,456)
Total liabilities and shareholders' equity (deficiency)	$ 3,783,879	1,406,970

The accompanying notes are an integral part of these financial statements

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

	2007	2006
Revenues	$ 1,258,017	$ 2,313,020
Cost of revenues	(943,385)	(1,965,074)
Gross profit	314,632	347,946
Operating expenses:		
Research and development	3,099,944	3,638,493
General and administrative	2,864,370	2,553,700
Stock based compensation research and development	230,668	219,895
Stock based compensation general and administrative	446,733	337,287
In-process research and development	-	981,819
Impairment of intangible assets	-	816,300
Total operating expenses	6,641,715	8,547,494
Loss from operations	(6,327,083)	(8,199,548)
Other income (expense):		
Interest income	164,847	41,510
Interest (expense)	(1,020)	(5,308)
Other (expense)	(1,387)	-
Total other income (expense)	162,440	36,202
Net loss	$ (6,164,643)	$ (8,163,346)
BasicnBasic and diluted net loss per share	$ (0.07)	$ (0.13)
Basic Basic and diluted weighted average common shares outstanding	90,687,677	63,759,092

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' (Deficiency)
For the years ended December 31, 2007 and 2006

	Common Stock		Additional Paid-In capital	AccumulatedDeficit
	Shares	Par Value		
Balance, January 1, 2006	50,612,504	$50,612	$86,045,192	($84,567,731)
Issuance of common stock	13,429,504	13,430	3,521,570	-
Issuance of common stock for exercise of options	504,100	504	112,816	-
Issuance of common stock to vendors	506,942	507	134,171	-
Issuance of warrants to vendors	-	-	121,965	-
Issuance of common stock for an equity commitment fee	512,500	512	(512)	-
Issuance of common stock to employees	222,061	222	82,632	-
Issuance of common stock to minority shareholders	3,068,183	3,068	978,750	-
Stock option expense	-	-	557,182	-
Net loss	-	-	-	(8,163,346)
Balance, December 31, 2006	68,855,794	68,855	91,553,766	(92,731,077)
Issuance of common stock	15,745,891	15,746	6,219,658	-

Issuance of common stock for exercise of options and warrants	8,195,487	8,195	2,128,088	-
Issuance of common stock to vendors	829,821	830	329,670	-
Issuance of stock to investors by contract as dilution protection	995,947	996	307,747	-
Issuance of common stock to employees	373,607	374	84,759	-
Stock option expense	-	-	677,401	-
Net loss	-	-	-	(6,164,643)
Balance, December 31, 2007	94,996,547	$94,996	$101,391,090	($98,895,720)

The accompanying notes are an integral part of these financial statements

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

	2007	2006
Operating activities		
Net loss	$ (6,164,643)	$ (8,163,346)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	119,565	137,044
Non-cash stock compensation	1,401,777	896,680
Non-cash stock purchase of in-process research and development	-	981,819
Impairment expense for intangibles	-	816,300
Change in operating assets and liabilities:		
Grants receivable	(7,912)	474,397
Prepaid expenses	(24,708)	44,324
Accounts payable	(1,264,868)	476,605
Accrued compensation	(57,044)	254,347
Accrued royalties	-	(60,000)
Total adjustments	166,810	4,021,516
Net cash used by operating activities	(5,997,833)	(4,141,830)
Investing activities:		
Purchases of office and laboratory equipment	(7,170)	(2,552)
Acquisition of intangible assets	(356,192)	(206,004)
Net cash used by investing activities	(363,362)	(208,556)
Financing activities:		
Net proceeds from issuance of common stock	6,235,404	3,535,000
Proceeds from exercise of warrants	1,592,263	-
Proceeds from exercise of stock options	634,020	113,320
Net cash provided by financing activities	8,461,687	3,648,320
Net increase (decrease) in cash and cash equivalents	2,100,492	(702,066)
Cash and cash equivalents at beginning of period	119,636	821,702
Cash and cash equivalents at end of period	$ 2,220,128	$ 119,636
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 1,020	$ 3,170
Non-cash transactions:		
Non-cash payment to an institutional investor	$ -	$ 220,374

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Nature of Business

The Company is a late stage biopharmaceutical company incorporated in 1987, focused on the development of biodefense vaccines and biotherapeutic products intended for areas of unmet medical need. DOR's biodefense business segment consists of converting biodefense vaccine programs from early stage development to advanced development and manufacturing. DOR's biotherapeutic business segment consists of development of orBec®, oral BDP, and other biotherapeutics products namely OraprineTM, LPMTM-Leuprolide, and LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs.

During the year ending December 31, 2007, the Company had one customer, the U.S. Federal Government. All revenues were generated from two active U.S. Federal Government Grants. As of December 31, 2007 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration. The amounts were billed in the month subsequent to year end. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, they are charged to operations when that determination is made.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. The Company makes 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, all outside legal and filing costs incurred in the procurement and defense of patents are capitalized.

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.

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from DOR's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company recorded impairment of intangible assets of $0 and $816,300 for the years ended December 31, 2007 and 2006, respectively.

Fair Value of Financial Instruments

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

Revenue Recognition

All of the Company's revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when DOR incurs internal expenses that are related to the grant.

Research and Development Costs

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

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, "Share-Based Payment," effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company has adopted SFAS No. 123R using the "modified prospective application" and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. As a result of adopting SFAS No. 123R, the Company's net loss for the year ended December 31, 2007 was $677,401 and for December 31, 2006 was $557,182 higher than if it had continued to account for share-based compensation under APB No. 25. Of these amounts $230,668 was for Research and Development and $446,733 was for General and Administrative in 2007 and $219,895 was for Research and Development and $337,287 was for General and Administrative in 2006. Stock based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. At December 31, 2007, the total compensation cost for stock options not yet recognized was approximately $600,000.

The fair value of each option grant at the years ended December 31, 2007 and December 31, 2006 are estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. 3,375,000 stock options were granted for the year ended December 31, 2007 and 4,360,000 stock options were granted for the year ended December 31, 2006.

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.27 and $0.30 for 2007 and 2006 respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 100% and 105% in 2007 and 2006, respectively and average risk-free interest rates of 4.5% and 4.76% in 2007 and 2006, respectively.

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

As stock options are exercised common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. Shares are issued from the 1995 or 2005 stock option plan and increase the number of shares the Company has outstanding.

Shares repurchased

The Company from time to time evaluates whether to repurchase existing common stock shares in the marketplace. This repurchased stock would be reflected as Treasury Stock. At this time we have no plans to repurchase the Company stock.

Income Taxes

The Company files a consolidated federal income tax return and utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their

respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2007 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

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

Use of Estimates and Assumptions

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

New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS No. 157”) which defines fair value, establishes a framework for measuring fair value and expands disclosure about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company has adopted SFAS No. 157 on January 1, 2008, as required, and is currently evaluating the impact of such adoption on its financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes” (“FIN 48”), which is an interpretation of SFAS No. 109, “Accounting for Income Taxes.” FIN 48 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company has adopted the provisions of FIN 48 effective January 1, 2007.

In February 2007, the FASB issued SFAS 159, “The Fair Value Option for Financial Assets and Financial Liabilities” (“SFAS 159”). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), “Business Combinations” (“SFAS 141(R)”). This Statement provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to recognize all assets acquired and liabilities assumed in the transaction, establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed, and requires the acquirer to disclose the nature and financial effect of the business combination. The Company is currently assessing the impact to the Company’s consolidated financial position, cash flows or results of operations upon adoption of SFAS 141(R).

In December 2007, the FASB issued SFAS No. 160, “Non-controlling Interests in Consolidated Financial Statements” (“SFAS 160”). This Statement amends Accounting Research Bulletin No. 51, Consolidated Financial Statements, to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 141(R) and SFAS 160 are required to be adopted simultaneously and are effective for the first annual reporting period beginning on or after December 15, 2008, with earlier adoption being prohibited. The Company is currently assessing the impact to the Company’s consolidated financial position, cash flows or results of operations upon adoption of SFAS 160.

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3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At December 31, 2007, the Company had working capital of $1,243,638, and a net loss of $6,164,643. In the twelve months ended December 31, 2007, the Company raised a total of approximately $8,726,000, $6,500,000 of which through equity financings and approximately $2,226,000 from warrant and stock option exercises. Subsequent to December 31, 2007, the Company closed on an equity financing of $658,000 from Fusion Capital and other investors. Additionally, in February 2008 the Company initiated a 25 month, $8,000,000 equity line of credit with Fusion Capital. The Company expects to sustain additional losses over the next twelve months. The Company's ability to raise additional funding may be more difficult due to its receipt of a not approvable letter from the FDA on its NDA for orBec®.

If the Company is unable for whatever reason to utilize its equity facility with Fusion and there were no other sources of financing, an austerity plan with reductions or discontinuation of operations of several of the Company's programs will be required. In an austerity plan, the Company would have to suspend clinical trials of orBec®/oral BDP for the treatment of GI GVHD and radiation enteritis, and reduce headcount and overhead. If this should occur, the Company believes it could continue to operate over the next four quarters at a reduced level and continue with its active programs, namely orBec® for the prevention of GVHD, its oral BDP radiation injury program, and its biodefense programs, all of which are supported by existing grants.

Management's plan to generate positive cash flows includes the following:

- The Company secured a new $8,000,000 equity line from Fusion Capital and the Company expects that the registration statement supporting this facility will become effective by April 2008.
- The Company will manage its expenditures very closely and proceed with Clinical programs with the use of the equity facility.
- The Company plans to continue seeking grant funds and responding to requests for proposals from governmental sources.
- The Company will utilize Named Patient Sales (Compassionate Use programs) wherever possible in countries outside the United States to generate revenues from orBec®. The Company already has letters of intent for Named Patient programs in place in South Korea, Australia, New Zealand and South Africa and expects to receive modest revenues from these programs in the second half of 2008.
- The Company is exploring outlicensing opportunities for orBec® and for its BioDefense programs both in the US and Europe.
- The Company has engaged Investment Bankers to assist in exploring mergers and acquisitions opportunities.

It is possible that the Company will seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, and develop new products and services and to support new strategic partnerships.

There is no assurance that the Company will be able to successfully implement its plan or will be able to generate cash flows from either operations, partnerships, or from equity financings.

4. Office and Laboratory Equipment

Office and laboratory equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following at December 31:

	2007	2006
Office equipment	$ 125,328	$ 117,660
Laboratory equipment	23,212	23,212
Total	148,540	140,872
Accumulated depreciation	(122,599)	(111,180)
	$ 25,941	$ 29,692

Depreciation expense was $10,781 and $17,593 for the years ended December 31, 2007 and 2006.

5. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2007				
Licenses	12.7	$ 462,234	$ 115,681	$ 346,553
Patents	9.7	1,633,490	659,256	974,234
Total	10.4	$ 2,095,724	$ 774,937	$ 1,320,787
December 31, 2006				
Licenses	13.7	$ 462,234	$ 88,443	$ 373,791
Patents	8.8	1,277,157	577,709	699,448
Total	10.1	$ 1,739,391	$ 666,152	$ 1,073,239

Amortization expense was $108,784 in 2007 compared to $119,451 for 2006.

Based on the balance of licenses and patents at December 31, 2007, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2008	$ 125,000
2009	126,000
2010	127,000
2011	128,000
2012	129,000

License fees and royalty payments in connection with the below agreements are expensed annually.

In July 2003, the Company entered into an exclusive license agreement with University of Texas South Western (UTSW) for administering the ricin vaccine via the intramuscular route for initial license fees of 250,000 shares valued at $200,000 of DOR common stock and $200,000 in cash. Subsequently, the Company negotiated the remaining intranasal and oral rights to the ricin vaccine for $50,000 in annual license fees in subsequent years. The license agreements term is over the life of the patent.

On March 1, 2005, the Company signed a sponsored research agreement with UTSW extending through March 31, 2007 for $190,000 which will grant the Company certain rights to intellectual property.

In October 2003, the Company executed an exclusive license agreement with the University of Texas System (UTMB) for the use of luminally-active steroids, including beclomethasone dipropionate (BDP) in the treatment of irritable bowel syndrome. Pursuant to this agreement, the Company paid UTMB a license fee of $10,000 and also agreed to pay an additional $10,000 license fee expense each year. The Company also agreed to pay past and future patent maintenance costs. The cost for 2007 and 2006 were $3,575 and $14,012, respectively. The Company acquired a sublicense agreement and may receive payments on this sublicense in the event of the sublicensee reaching certain milestones.

In July 2006, the Company signed a sponsored research agreement for $37,500 with Thomas Jefferson University (TJU). In 2005, the Company signed a sponsored research agreement for $150,000. In May 2003, the Company signed a license agreement with TJU for the licensure of detoxified botulinum toxin for use as a vaccine. The Company paid TJU $30,000 in cash and issued 141,305 shares of common stock valued at $130,000. The Company also agreed to reimburse TJU for past and future patent maintenance. The patent maintenance expense for 2006 and 2005 was $74,260 and $35,665 respectively. The patent costs are capitalized. The Company is also responsible for a license maintenance fee of $10,000 in 2005 and $15,000 in 2006 and each year thereafter. These costs are expensed as incurred. The Company must also pay TJU $200,000, upon the first filing of any New Drug Application (“NDA”) with the United States Food and Drug Administration (“FDA”) and $400,000 upon first approval of an NDA relating to the first licensed product by FDA.

6. Shareholders' Equity

Preferred Stock

The Company has 5 million authorized shares of preferred stock, none are issued or outstanding.

Common Stock

On February 9, 2007, the Company completed the sale of 11,680,850 shares of DOR's common stock to institutional investors and certain of the Company's officers and directors for a purchase price of $5,490,000.

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction's dilutive nature, all investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders in that placement who still held shares of the Company's common stock were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. These investors, nor any others for that matter, hold any further anti-dilution rights. Because no agreement was reached by March 1, 2007, DOR was obligated to return the $2 million to Sigma-Tau by April 30, 2007. On June 1, 2007, the Company returned the $2 million to Sigma Tau.

On May 10, 2006, the Company completed a merger pursuant to which Enteron Pharmaceutical, Inc. ("Enteron"), the common stock of which the Company held 88.13% prior to the merger, was merged into a wholly-owned subsidiary of the Company. Pursuant to this transaction, the Company issued 3,068,183 shares of common stock to the Enteron minority shareholders in exchange for all of the outstanding common stock of Enteron that the Company did not already own. This transaction was accounted for as a purchase, and accordingly the Company recorded an in-process research and development expense of $981,819. The common stock was recorded at the shares' fair market value on the date of the merger.

On April 10, 2006, the Company completed the sale of 13,099,964 shares of common stock to institutional and other accredited investors for a purchase price, net of expenses, of $3,410,032. The investors also received warrants to purchase 13,099,964 shares of common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. The Company filed a registration statement with the Securities and Exchange Commission and it was declared effective on May 25, 2006.

On January 17, 2006, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. The Fusion facility allowed them to purchase on each trading day $20,000 of DOR common stock up to an aggregate of $6,000,000 million over approximately a 15-month period. As part of that agreement, DOR issued Fusion 512,500 shares of common stock as a commitment fee, the non-cash payment for this was $220,374 valued at the shares' fair market value. During 2006 Fusion purchased 329,540 common shares for $ 124,968. The 2006 Fusion Agreement expired after the 15 month term of the contract expired.

Stock Compensation to Employees and Non-employees

During the years ended December 31, 2007 and 2006, the Company issued 829,821 and 506,942 shares of common stock as payment to vendors for consulting services. An expense of $330,500 and $134,679 respectively was recorded, which approximated the shares' fair market value on the date of issuance. Additionally, in 2007 the Company issued 373,607 shares of common stock as part of severance payments. In 2006, the Company issued 207,896 shares of

common stock as part of severance payments to terminated employees and 165,711 shares of common stock to employees. An expense of $35,133 and $50,000 respectively was recorded, which approximated the shares' fair market value on the date of issuance. In 2006, the Company issued 193,413 shares of common stock as part of severance payments to terminated employees and 28,648 shares of common stock to employees. An expense of $75,979 and $6,875 respectively was recorded, which approximated the shares' fair market value on the date of issuance. These shares of common stock issued were covered by the Company's Form S-8 Registration Statement filed with the SEC on December 30, 2005 and amended in September 2007.

The dilutive nature of the Sigma-Tau transaction on January 3, 2007 required that all prior investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders who still held shares of the Company's common stock were issued 995,947 shares of the Company's common stock and the Company recorded an expense of $308,743. These investors, nor any others for that matter, hold any further anti-dilution rights.

For the twelve months ended December 31, 2007, 1,737,200 stock options were exercised to purchase shares of common stock which provided $633,895. For the corresponding period in 2006, 504,100 stock options were exercised to purchase shares of common stock which provided proceeds of $113,320.

7. Stock Option Plans and Warrants to Purchase Common Stock

Stock Options

The 2005 Equity Incentive Plan is divided into four separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant. In addition under the plan the Board may elect to pay certain consultants, directors, and employees in common stock. The Plan was amended in September 2007 to increase the number of options available under the plan to 20,000,000. The table below only accounts for transactions occurring as part of the amended 2005 Equity Incentive Plan.

December 31,	2007	2006
Shares available for grant at beginning of year	3,236,032	7,000,000
Increase in shares available	10,000,000	-
Options granted	(3,375,000)	(4,360,000)
Options forfeited or expired	1,140,000	1,325,000
Common stock payment for services	(388,071)	(728,968)
Shares available for grant at end of year	10,612,961	3,236,032

In 2007 and 2006, 1,487,200 and 504,100, respectively, options were exercised that were covered under the 1995 plan.

The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2007 and 2006 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at January 1, 2006	10,014,339	$ 0.59
Granted	4,360,000	0.30
Forfeited	(2,230,900)	0.83
Exercised	(504,100)	0.22
Balance at December 31, 2006	11,639,339	0.59
Granted	3,375,000	0.46
Forfeited	(2,927,300)	0.73
Exercised	(1,737,200)	0.36
Balance at December 31, 2007	10,349,839	$ 0.44

The weighted-average exercise price, by price range, for outstanding options at December 31, 2007 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.20-$0.50	8.12	9,020,000	5,884,756
$0.51-$1.00	2.69	962,839	962,839
$1.01-$6.00	3.17	367,000	367,000
Total	7.53	10,349,839	7,214,595

Stock options are issued at the market price on the date of issuance. Stock options issued to directors fully vest upon issuance. Stock options issued to employees generally vest 25% upfront, then 25% each year for a period of three years. Stock options are issued over each three month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals are employees or directors. In general when an employee or director terminates employment the options will expire within three months.

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From time to time, the Company grants warrants to consultants and grants warrants to purchase common stock in connection with private placements.

Warrants to purchase common stock

Warrant activity for the years ended December 31, 2007 and 2006 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at January 1, 2006	22,167,118	$ 0.92
Granted	14,961,672	0.25
Balance at December 31, 2006	37,128,790	0.65
Granted	560,106	0.59
Expired	(2,178,909)	1.90
Exercised	(6,458,287)	0.25
Balance at December 31, 2007	29,051,700	$ 0.70

During 2006, 500,000 warrants to purchase common stock were issued to vendors and an expense in the amount of $121,965 was recorded.

During 2008, approximately 10,000,000 of the Company's existing warrants will expire. By April 2009, a total of approximately 20,000,000 of the Company's existing warrants will expire.

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2007 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.24-$0.50	1.23	8,503,386	8,503,386
$0.505-$1.00	1.67	18,328,622	18,328,622
$1.01-$2.00	0.29	2,012,622	2,012,622
$8.11	0.86	207,070	207,070
Total	1.44	29,051,700	29,051,700

8. Income Taxes

Deferred tax assets as of December 31:

	2007	2006
Deferred tax assets:		
Net operating loss carry forwards	$ 25,000,000	$25,000,000
Orphan drug and research and development credit carry forwards	2,000,000	3,000,000
Other	3,000,000	3,000,000
Total	30,000,000	31,000,000
Valuation allowance	(30,000,000)	(31,000,000)
Net deferred tax assets	$ -	$ -

At December 31, 2007, the Company had net operating loss carry forwards of approximately $73,000,000 for Federal and state tax purposes, which are currently expiring each year until 2026.

The net change in the valuation allowance for the year ended December 31, 2007 and December 31, 2006 was an increase of approximately $6,000,000 and $5,000,000 respectively, resulting primarily from net operating losses generated. Based on ownership changes that have and may occur, future utilization of the net operating loss carry forwards may be limited.

The following is the approximate amount of the Company’s tax credits and net operating losses that expire over the next five years:

2008	$ 910,000
2009	1,330,000
2010	1,410,000
2011	870,000
2012	3,870,000

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2007 and 2006 was as follows:

	2007	2006
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(4.29)	(3.63)
Permanent differences, principally purchased in-process research and development	-	3.30
Valuation allowance	38.29	34.33
Provision for income taxes (benefit)	- %	- %

Due to the move to of the corporate offices to New Jersey the Florida net operating loss is suspended.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to income tax assessment for years before 2004. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service (“IRS”) and state authorities for purposes of determining the amount of net operating losses to reduce taxable income generated in a given tax year.

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9. Risks and Uncertainties

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

10. Concentrations

During the year ended December 31, 2007, the Company had one vendor that constituted approximately 12% of the outstanding payables.

At December 31, 2007 and 2006, the Company had deposits in financial institutions that exceeded the amount covered by the Federal Deposit Insurance Company. The excess amounts at December 31, 2007 and December 31, 2006 were $2,020,128 and $19,636, respectively. These funds are held at a major Banking Institution.

11. Subsequent Events

On February 14, 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.5 million over approximately a 25-month period. As part of the agreement, the company issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. If DOR’s stock price exceeds $0.15, then the amount required to purchase may be increased under certain conditions as the price of DOR’s common stock increases. The Company cannot require Fusion Capital to purchase any shares of DOR’s common stock on any trading days that the market price of DOR’s common stock is less than $0.10.

12. Business Segments

The Company had two active segments for the year ended December 31, 2007 and December 31, 2006: BioDefense and BioTherapeutics. Summary data:

	December 31, 2007	2006
Net Revenues		
BioDefense	$ 2,173,128	$ 2,896,878
BioTherapeutics	139,892	178,858
Total	$ 2,313,020	$ 3,075,736
Loss from Operations		
BioDefense	$ (1,943,732)	$ (847,830)
BioTherapeutics	(5,061,664)	(1,665,812)
Corporate	(1,164,152)	(2,321,409)
Total	$ (8,199,548)	$ (4,835,051)
Identifiable Assets		
BioDefense	$ 849,295	$ 2,189,216
BioTherapeutics	343,876	420,250
Corporate	213,799	763,108
Total	$ 1,406,970	$ 3,372,574
Amortization and Depreciation Expense		
BioDefense	$ 103,855	$ 63,212
BioTherapeutics	24,395	118,351
Corporate	8,794	12,721
Total	$ 137,044	$ 194,284
Interest Income		
Corporate	$ 164,847	$ 41,510
Total	$ 164,847	$ 41,510
Stock Option Compensation		
BioDefense	$ 69,591	$ 98,937
BioTherapeutic	161,077	120,958
Corporate	446,733	337,287
Total	$ 677,401	$ 557,182

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SIGNATURES

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

DOR BIOPHARMA, INC.

By: / s/ Christopher J. Schaber
Christopher J. Schaber
President and Chief Executive Officer

Date: March 25, 2008

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated, on March 25, 2008.

Signature	Title	Date
/s/ Christopher J. Schaber Christopher J. Schaber	Director, President and Chief Executive Officer (Principal Executive Officer)	March 25, 2008
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Director, Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2008
/s/ James S. Kuo James S. Kuo	Chairman of the Board	March 25, 2008
/s/ Cyrille F. Buhrman Cyrille F. Buhrman	Director	March 25, 2008
/s/ James Clavijo James Clavijo	Controller, Treasurer, and Corporate Secretary	March 25, 2008

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