DOR BIOPHARMA INC
Form 10-K
March 30, 2009

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2008

[ ] 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)
29 Emmons Drive Suite C-10 Princeton, NJ	08540
(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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No R

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes £ No R

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 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 R No £

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this 10-K or any amendments to this Form 10-K. R

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer £	Accelerated filer £	Non-accelerated filer £	Smaller reporting company R

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes £ No R

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $18,000,000 (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 June 30, 2008.

At March 25, 2009, 167,070,944 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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PART I

Item 1. Business.

This Annual Report on Form 10-K 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 developing products to treat life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need; as well as several biodefense vaccines. We maintain two active business segments: BioTherapeutics and BioDefense. Our business strategy is to:

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
(b) identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") to commercialize orBec® in the U.S., Canada and Mexico, we will be paid a 35% royalty on net sales in these territories by Sigma-Tau and they will be responsible for the expense associated with all launch preparation and post-approval sales and marketing activities;
(c) conduct a Phase 2 clinical trial of orBec® for the prevention of acute Graft-versus-Host disease ("GVHD");
(d) evaluate and initiate additional clinical trials to explore the effectiveness of oral beclomethasone dipropionate (oral "BDP") in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as radiation enteritis, radiation injury and Crohn's disease;
(e) make orBec® available worldwide through named patient access programs ("NPAP") for the treatment of acute GI GVHD;
(f) reinitiate development of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) 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;
(i) acquire or in-license new clinical-stage compounds for development; and
(j) explore other business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company.

1. BioTherapeutics Overview

orBec®

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GI GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970's as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® is specifically formulated for oral administration as a single product consisting of two tablets; one tablet is intended to

release BDP in the proximal portions of the GI tract, and the other tablet is intended to release BDP in the distal portions of the GI tract.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® also benefits from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, which provide for seven and 10 years of post-approval market exclusivity, respectively.

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Clinical and Regulatory History

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support orBec's® ability to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the US and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time to treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). At one year post randomization in the pivotal Phase 3 trial, 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, p=0.04).

In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients at Day 30 (the end of treatment) had a durable GVHD treatment response as measured by whether or not they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the orBec® and placebo groups, respectively (p-value 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) vs. 5 of 29 (17%) in the orBec® and placebo groups, respectively (p-value 0.007).

Based on the data from Phase 2 and the Phase 3 studies, on September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® with the U.S. Food and Drug Administration ("FDA") for the treatment of acute GI GVHD. On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") for orBec® with the European Central Authority, the European Medicines Evaluation Agency ("EMEA"). On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute 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 FDA guidance from that meeting in which 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, and that the FDA would be agreeable to reviewing a plan for a Treatment Investigational New Drug ("Treatment IND") as long as it does not interfere with patient accrual in a confirmatory trial. In May 2008, we voluntarily withdrew the MAA that was being reviewed by EMEA. We reached this decision after consultation with the EMEA and determining that confirmatory evidence of clinical efficacy will be required for approval. This is consistent with the request made by the FDA. The withdrawal of an MAA application does not prejudice the possibility of making a new application at a later stage.

We recently reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial's design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the FDA can only change a SPA for very limited reasons. Based on data from the prior Phase 3 study of orBec®, the upcoming confirmatory Phase 3 protocol will be a highly powered, double-blind, randomized, placebo-controlled, multi-center trial and will seek to enroll an estimated 166 patients. The primary endpoint is the treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-value = 0.005) in the previous Phase 3 study as a key measure of durability following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment).

We have entered into a collaboration agreement with Numoda Corporation ("Numoda"), for the execution of our upcoming confirmatory, Phase 3 clinical trial of orBec®. Collaborating with Numoda will allow us to take advantage of a scope of services including using their industry benchmarking capabilities to develop an operational and financial plan including the use of a proprietary management and oversight capabilities process. Barring any unforeseen modifications to the Phase 3 clinical program, Numoda will guarantee the agreed clinical trial budget against cost overruns. As part of the collaboration, Numoda has agreed to accept payment in our common stock in exchange for a portion of its services in connection with the conduct of the upcoming confirmatory Phase 3 clinical trial. To date, we have issued 347,222 shares of common stock to Numoda in partial payment for its services. Working with Numoda, we also will be able to take full advantage of early reporting of results to potential licensing partners and others. We expect to begin enrollment in the confirmatory Phase 3 trial in the second half of 2009.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico (the Territory). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment, of $1 million, will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay us a 35% royalty on net sales in the Territory, as well as pay for commercialization expenses, including launch activities.

In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price is equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,666,667 common shares at $0.09 per share (the market price at the time) for proceeds of $1,500,000 in exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009. As part of these transactions, we granted Sigma-Tau certain demand and piggy-back registration rights. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. They have both prescription and consumer products in metabolic, oncology, renal and supplements.

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On November 25, 2008, we announced that the Therapeutics Goods Administration of Australia designated orBec® as an Orphan Drug for the treatment of patients with GI GVHD following allogeneic hematopoietic cell transplantation.

On September 10, 2008, we announced that we entered into a collaboration agreement with BurnsAdler Pharmaceuticals, Inc. ("BurnsAdler"), a specialty pharmaceutical company based in North Carolina under which BurnsAdler will act as our distributor of a NPAP for orBec® to patients suffering from acute GI GVHD in all countries within Central America, South America and the Caribbean (Latin America). On October 30, 2008 we announced that we expanded our collaboration with BurnsAdler, as our distributor of orBec® to patients suffering from acute GI GVHD in Canada via the Special Access Programme.

On August 27, 2008, we announced that we entered into a collaboration agreement with Pacific Healthcare Thailand Co., Ltd. ("Pacific"), a specialty pharmaceutical company based in Bangkok, under which Pacific will act as our sponsor to administer an NPAP for orBec® to patients suffering from acute GI GVHD in Thailand as well as other Association of Southeast Asian Nations (ASEAN) member countries including Brunei, Cambodia, Indonesia, Laos, Myanmar, Philippines and Vietnam.

On July 18, 2008, we announced that we entered into collaboration agreement with Steward Cross Pte Ltd ("Steward Cross"), a specialty pharmaceutical company based in Singapore, under which Steward Cross will act as our Sponsor to administer an NPAP for patients suffering from acute GI GVHD in Singapore and Malaysia. We will manufacture and supply orBec® to Steward Cross, while Steward Cross will be responsible for all distribution costs in Singapore and Malaysia.

On July 15, 2008, we announced that we entered into a definitive collaborative agreement with IDIS Limited ("IDIS"), under which IDIS will act as our sponsor to administer an NPAP for patients suffering from acute GI GVHD in the European Union. IDIS is the leading specialist in the management of NPAPs in Europe.

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 an NPAP for orBec® to patients suffering from acute GI GVHD in South Korea.

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 an NPAP for orBec® to acute GI GVHD patients in Australia, New Zealand and South Africa.

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of 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 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 direct monetary benefit from this grant, but if successful, this funded trial could serve to increase the value of our orBec®/oral BDP program. 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 this study will begin dosing at the start of the conditioning regimen and continue through day 75 following HCT. Enrollment in this trial is expected to be completed in the second half of 2009.

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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 this 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).” 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 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 this 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.

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, p=0.04). 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 (p=0.03).

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 Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo.

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Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50 percent of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

On December 1, 2008, we received $1.5 million under a non-binding letter of intent with 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 pipeline compounds until March 1, 2009. 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.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of Beclomethasone Dipropionate (orBec®). Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico. Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of $1 million will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay us a 35% royalty on net sales, as well as pay for commercialization expenses, including launch activities.

Research and Development Analysis for orBec®

Since 2000, we have incurred expenses of approximately $16,000,000 in the development of orBec®. Research and development costs for orBec® totaled $933,561 for the 12 months ended December 31, 2008 and $2,288,615 and $3,060,778 for the years ended December 31, 2007 and 2006, respectively.

About GVHD

GVHD 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 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. 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 acute GI GVHD. Currently used systemic immunosuppressives utilized to control GI GVHD substantially inhibit the highly desirable Graft-versus-Leukemia (“GVL”) effect of bone marrow transplantations, 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 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 GVL 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.

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 and treating 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 Crohn's Disease, Lymphocytic Colitis, Irritable Bowel Syndrome, Ulcerative Colitis, among other indications.

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DOR 201

On December 8, 2008, we announced that the FDA has completed its review and cleared the Investigational New Drug ("IND") application for DOR201, a time-release formulation of oral BDP, for the prevention of acute radiation enteritis. Consequently, we are able to initiate a Phase 1/2 clinical trial in acute radiation enteritis, expected to occur in the second half of 2009. On January 6, 2009, we also announced that DOR201 also received "Fast Track" designation from the FDA. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit an NDA for DOR201 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

DOR201 contains BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in inhalation products for the treatment of patients with allergic rhinitis and asthma. BDP is also the active ingredient in orBec®, currently in Phase 3 and Phase 2 development by DOR for the treatment and prevention of GI GVHD, respectively. DOR201 is time-release formulation of BDP specifically designed for oral use. We plan to initiate a Phase 1/2 clinical trial in acute radiation enteritis in the second half of 2009.

About Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectum, prostate, and vagina. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B12 are not well absorbed.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

There are over 100,000 patients in the U.S. annually who receive abdominal or pelvic external beam radiation treatment for cancer who are at risk of developing acute and chronic radiation enteritis.

2. BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin toxin vaccine to be clinically tested in humans. Ricin is a potent glycoprotein toxin derived from the beans of castor plants. It can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control ("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.

We have announced positive Phase 1 clinical trial results for RiVax™ which demonstrated that the vaccine is well tolerated and induces antibodies in humans that neutralize the ricin toxin. The functional activity of the antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injected with serum samples from the volunteers. The outcome of the study was published in the Proceedings of the National Academy of Sciences. A second Phase 1 trial is currently underway, utilizing the adjuvanted formulation.

The initial Phase 1 clinical trial was conducted by Dr. Ellen Vitetta at the University of Texas Southwestern Medical Center ("UTSW") at Dallas, DOR's academic partner on the RiVax™ program. The National Institutes of Health ("NIH") has awarded us two grants one for $6.4 million and one for $5.2 million for a total of $11.6 million for the development of RiVax™ covering process development, scale-up and cGMP manufacturing, and preclinical toxicology testing pursuant to the FDA's "animal rule."

The development of RiVaxTM 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. This 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.

On April 29, 2008, we announced the initiation of a comprehensive program to evaluate the efficacy of RiVax™, in non-human primates. This study is taking place at the Tulane University Health Sciences Center and will provide data that will further aid in the interpretation of immunogenicity data obtained in the human vaccination trials. The study was initiated in the second quarter of 2008.

On January 29, 2008, we announced that we 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. 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.

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 is found by WRAIR's studies, which they are funding. If successful, this will enhance the value of our RiVax™ product and assist with continuing the progression of the program.

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 UTSW 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 UTSW. 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. UTSW began a second Phase 1 human clinical trial with RiVaxTM in August of 2008.

Research and Development Analysis for RiVax™

The costs that we have incurred to develop RiVax™ since 2002 total approximately $6,900,000. Research and development costs for RiVax™ totaled $312,486 for the 12 months ended December 31, 2008 and $1,350,364 and $2,130,516 for the years ended December 31, 2007 and 2006, respectively. Of the amount spent during the years ended December 31, 2007 and 2006, $897,470 and $1,128,257 were for costs reimbursed under the NIH grant, respectively.

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BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, originated 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 July 2007, we announced that the first results from testing of a multivalent form of BT-VACCTM were published in the journal Infection and Immunity (Ravichandran et al., 2007, Infection and Immunity, v. 75, p. 3043). These results are the first to 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. The combination vaccine also can induce protection when given mucosally as a booster to animals that have been given a primary vaccine 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. This program is currently ongoing and 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 oral or intranasal route that we are developing potentially provides a self administration option, which would offer the distinct advantage of bypassing the requirement for needles and personnel to administer the vaccine.

Research and Development Analysis for BT-VACC™

The costs that we have incurred to develop BT-VACC™ from 2002 total approximately $2,300,000. Research and development costs for BT-VACC™ totaled $201,529 for the 12 months ended December 31, 2008 and $360,997 and $130,381 for the years ended December 31, 2007 and 2006, respectively. Of the amount spent during the years ended December 31, 2007 and 2006, $45,915 and $4,000 were for costs reimbursed under the under the SBIR grant, respectively.

Anthrax Vaccine Option

On May 8, 2008, we entered into a one-year exclusive option with the President and Fellows of Harvard College to license analogues of anthrax toxin for prospective use in vaccines against anthrax, a potentially fatal disease caused by the spore-forming, gram-positive bacterium Bacillus anthracis. The option, which was obtained through negotiation with Harvard University's Office of Technology Development, encompasses an issued U.S. patent that covers engineered variants of protective antigen ("PA") developed in the Harvard Medical School laboratory of Dr. John Collier. PA is the principal determinant of protective immunity to anthrax and is being developed for second- and third-generation anthrax vaccines. There has been a major effort on the part of the federal government to develop vaccines for use both pre- and post-exposure to improve upon the vaccine currently in use. This vaccine, known as AVA (for anthrax vaccine adsorbed), consists of a defined, but impure mixture of bacterial components. AVA is FDA approved, but requires multiple injections followed by annual boosters. Vaccines such as AVA or those based on the purified, recombinant anthrax toxin component PA ("rPA") induce antibodies that neutralize anthrax holotoxin and can strongly protect animals from inhaled anthrax spores. Several of the protein variants developed by Dr. Collier have been shown to be more immunogenic than native rPA, perhaps because they are processed more efficiently by cellular antigen processing pathways. We believe that with government funding we will be able to develop the Collier anthrax vaccine into one with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. We do not intend to conduct any new research and development or commit any funds to this program until we receive grant funding.

3. Additional Programs

LPMTM - Leuprolide

Our Lipid Polymer Micelle ("LPM™") oral drug delivery system is a proprietary 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. The LPM™ system 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.

In preclinical studies, the 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, 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 2009 to confirm these findings.

An oral version of leuprolide may 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 Analysis for LPM™ Leuprolide

The costs that we have incurred to develop LPM™-Leuprolide since 2000 total approximately $1,400,000. Research and development costs for LPM™-Leuprolide totaled $112,246 for the 12 months ended December 31, 2008 and $38,254 and $5,679 for the years ended December 31, 2007 and 2006, respectively. 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 U.S. 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. We anticipate filing an ANDA; however this program is suspended pending further funding from financing or partnerships.

Research and Development Analysis for OraprineTM

The costs that we have incurred to develop Oraprine™ since 2000 total approximately $400,000. Research and development costs for Oraprine™ totaled $4,500 for the 12 months ended December 31, 2008 and $5,100 and $6,996 for the years ended December 31, 2007 and 2006, respectively. These costs are mainly legal costs in connection with maintenance of our patent positions.

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4. 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	PIvotal Phase 3 confirmatory trial to be initiated in 2009
orBec®	Prevention of Acute GI GVHD	Phase 2 trial enrolling
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial potentially to be initiated in 2009
Oral BDP	Radiation Enteritis and Radiation Exposure	Phase 1/2 trial potentially to be initiated in 2009
LPMTM – Leuprolide	Endometriosis and Prostate Cancer	Phase 1 trial potentially to be initiated in 2009
OraprineTM	Oral lesions resulting from GVHD	Ready for Phase 1/2 trial

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 Second Phase 1 trial enrolling
Botulinum Toxin	No vaccine or antidote currently FDA approved	Oral/Nasal Botulinum Vaccine

5. The Drug Approval Process

General

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FDA and applicable agencies in other countries. Testing, manufacturing, commercialization, advertising, promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation by government authorities in the U.S. 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 U.S., mandatory procedures and safety standards, approval processes, manufacturing and marketing practices established by the FDA must be satisfied.

An IND application is required before human clinical testing in the U.S. of a new drug compound or biological product can commence. The INDA 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 U.S., 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 the development of biodefense vaccines 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 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 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.

1. Marketing Strategies

Pursuant to the collaboration and supply agreement with Sigma-Tau, we granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico.

We are actively seeking a commercialization partner for orBec® and oral BDP outside of North America as well as for our LPMTM – Leuprolide and OraprineTM programs.

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 U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

Competition

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

Biodefense Vaccine Competition

We face competition in the area of biodefense vaccines 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 the 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.

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 GVHD. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat GVHD. 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 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 addition, Salix Pharmaceuticals, Inc. markets an FDA approved therapy for ulcerative colitis called Colazal®. Chiesi Pharmaceuticals ("Chiesi") markets a delayed release oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPERTM for ulcerative colitis and may seek marketing approval in Italy and other European countries. In the U.S., Eurand N.V. ("Eurand") has licenses from Chiesi to the same formulation as CLIPPERTM and is developing it for ulcerative colitis. Eurand has also received Orphan Drug Designation for the compound in pediatric ulcerative colitis patients.

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.

2. 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 U.S. 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 are the exclusive licensee of an issued U.S. patent that covers the use of orBec® for the prevention and treatment of GI GVHD. We also have “Orphan Drug” designations for orBec® in the U.S. 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.

orBec® License Agreement

In November 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 $80,000 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 oral BDP.

Ricin Vaccine Intellectual Property

In January 2003, we executed a worldwide exclusive option to license patent applications with 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 U.S. Patent and Trademark Office 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™.

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 in 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, which increased to $15,000 in 2006 and every year thereafter.

3. Employees

As of December 31, 2008, we had seven full-time employees, three of whom are Ph.D.s.

4. Research and Development Spending

We spent approximately $1,600,000 and $3,100,000 in the years ended December 31, 2008 and 2007, respectively, on research and development.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements 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-K 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-K 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, 2008, we had $1,475,466 in cash available. Since December 31, 2008, we have issued a total of 62,580,702 shares of common stock and warrants to purchase up to 20,914,035 shares of common stock raising a sum of $8,384,200. Based on our projected budgetary needs and funding from the existing grants over the next 18 months, we expect to be able to maintain the current level of our operations into the third quarter of 2010 and conduct the pivotal Phase 3 confirmatory clinical trial of orBec® for the treatment of acute GI GVHD.

We have sufficient funds through our existing, biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institute 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. Our biodefense grants have an overhead component that allows us an agency approved percentage over our incurred costs. We estimate that the overhead component, (which is approximately 21% above our subcontracted expenses and includes funds for direct employees working on the grants), from our existing NIH biodefense grants will generate approximately $600,000 over the next four quarters.

Our products are positioned for or are currently in preclinical studies or clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. Through December 31, 2008, we had expended approximately $24,200,000 developing our current product candidates for preclinical research and development and

clinical trials, and we currently expect to spend at least $9 million over the next two years in connection with the development and commercialization of our therapeutic and vaccine products, licenses, employment 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 through our existing equity facility with Fusion Capital Fund II, LLC ("Fusion Capital") or another financing source to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

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

- we may 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 may encounter problems in clinical trials or Named Patient Access programs; or
- the technology or product may 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 U.S., 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 acute 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 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 anticipated working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's "Special Protocol Assessment" process; and (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.

On January 5, 2009, we reached an agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA's Special Protocol Assessment procedure. We expect to begin enrollment in the new confirmatory Phase 3 clinical trial for the treatment of acute GI GVHD in the second half of 2009.

Although we intend to obtain FDA approval for orBec®, there can be no assurances that the FDA will ever approve orBec® for market launch. Furthermore, the FDA may mandate additional testing or data, which may take additional time and expense to provide.

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 U.S. 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 vaccines we are 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 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 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.

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, which material will be used 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.

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.

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

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. Although we have a collaboration agreement with Sigma-Tau for the sales and marketing of orBec® in North America, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In Addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially 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.

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 MD 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 additional 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 additional 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. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America. Development of an effective sales force in any part of the world 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 U.S. Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. 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 nine employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. 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; Dr. Robert Brey, our Chief Scientific Officer was hired in 1996; Dr. Brian L. Hamilton, our Chief Medical Officer, was hired in March 2009; and James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. In June 2007, Cyrille F. Buhrman was appointed to the Board of Directors. In March 2009, Gregg Lapointe was appointed 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.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows

During recent months, there has been substantial volatility and a decline in financial markets due at least in part to the deteriorating global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by the current economic crisis. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.

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 by us or others of results of pre-clinical testing and clinical trials;
- 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;
- 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 the Company, 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, 2005 through December 31, 2008 with the per share price of our common stock ranging between a high of $0.95 per share to a low of $0.04 per share. As of March 25, 2009, our common stock traded at $0.11. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

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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 OTCBB securities market on April 18, 2006 under the ticker symbol DORB. Our stock was delisted from the AMEX because we did not maintain stockholder equity above $6,000,000, as required under the maintenance requirement for continued listing. 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 on the OTCBB must be current in their reports filed with the Securities and Exchange Commission (the "SEC") and other regulatory authorities.

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.

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 43,500,000 shares of our common stock at a current weighted average exercise price of approximately $0.20; and

- options to purchase approximately 16,370,039 shares of our common stock at a current weighted average exercise price of approximately $0.27.

During 2009, outstanding warrants to purchase approximately 10,580,000 shares of our common stock will expire.

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 up to 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 3,864,987 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 $627,500. Additionally, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In addition to the shares already sold to

Fusion Capital, we have filed a registration statement with respect to approximately 18.8 million shares that are available to be sold to Fusion Capital. We may ultimately sell all, some or none of the 18.8 million shares of common stock. If such 18.8 million shares were issued and outstanding as of March 25, 2009, the 18.8 million shares would have represented approximately 13.5% of the total outstanding common stock.

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.

On February 14, 2008, we entered into an $8,500,000 common stock purchase agreement with 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 at $0.22 per share, for an aggregate price of $500,000. To date, we have issued an additional 1,012,209 shares of common stock and received an additional $127,500 from the Fusion Capital facility.

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 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 registered for sale by Fusion Capital are freely tradable. It is anticipated that those shares will be sold over a period of up to 25 months from the date of the prospectus pertaining to those shares. Depending upon market liquidity at the time, a sale of shares under the 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 approximately 18.8 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.

The common stock purchase agreement with Fusion Capital also may be terminated in the event of a default under the agreement. In addition, we cannot 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. The closing price of our common stock on March 25, 2009, was $0.11.

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. Properties

We currently lease approximately 2,500 square feet of office space at 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628. The office space currently serves as our corporate headquarters. We pay rent of approximately $5,800 per month, or $28 per square foot, on a month-to-month lease, which was entered into on October 1, 2008. We anticipate that we will move into a new facility in the second quarter of 2009.

Item 3. Legal Proceedings

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.

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

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is quoted on the Over-the-Counter-Bulletin-Board (“OTCBB”) under the symbol "DORB." 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, 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
Fiscal Year Ended December 31, 2008:		
First Quarter	$0.25	$0.16
Second Quarter	$0.19	$0.11
Third Quarter	$0.15	$0.09
Fourth Quarter	$0.12	$0.04

As of March 25, 2009, the last reported price of our common stock quoted on the OTCBB was $0.11 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 1,076 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. Selected Financial Data.

Not applicable.

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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. Business-Risk Factors" in this Annual Report. See "Item 1. Business-Cautionary Note Regarding Forward-Looking Statements."

Business Overview and Strategy

We are a research and development biopharmaceutical company focused on developing products to treat life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need; as well as several biodefense vaccines. We were incorporated in Delaware in 1987. We maintain two active business segments: BioTherapeutics and BioDefense.

Our business strategy is to:

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
(b) identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") to commercialize orBec® in the U.S., Canada and Mexico, Sigma-Tau will pay us a 35% royalty on net sales in these territories and they will be responsible for the expense associated with all launch preparation and post-approval sales and marketing activities;
(c) conduct a Phase 2 clinical trial of orBec® for the prevention of acute Graft-versus-Host disease ("GVHD");
(d) evaluate and initiate additional clinical trials to explore the effectiveness of oral beclomethasone dipropionate (oral "BDP") in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as radiation enteritis, radiation injury and Crohn's disease;
(e) make orBec® available worldwide through named patient access programs ("NPAP") for the treatment of acute GI GVHD;
(f) reinitiate development of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) 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;
(i) acquire or in-license new clinical-stage compounds for development; and
(j) explore other business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company.

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 U.S. 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. We evaluate these estimates and judgments on an on-going basis.

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 or if the underlying program is no longer being pursued. 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 legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy 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 capitalize intangible assets that have alternative future uses as this is common practice in the pharmaceutical development industry. Of our intangible asset balance, our purchase of the RiVaxTM vaccine license from the University of Texas Southwestern Medical Center for $462,234 was for up-front license costs. 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.

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

Our revenues are generated from U.S. government grants and from NPAP sales of orBec®. The government grants are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. The NPAP revenues are recorded when orBec® is shipped.

Stock Based Compensation

From time to time we issue common stock to vendors, consultants, and employees as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must

file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

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.

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Material Changes in Results of Operations

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007.

For the 12 months ended December 31, 2008, we had a net loss of $3,422,027 as compared to a net loss of $6,164,643 for the 12 months ended December 31, 2007, for a decrease of $2,742,616, or 44%. This decrease is primarily attributed to lower research and development costs and lower costs associated with preparation of FDA and European regulatory matters as well as a reduction in general and administrative expenses, such as, public and investor relation expenses, a reduction in employee, travel and consultant expenses, lower expenses for stock based compensation in the amount of $291,785, and the dilution expense taken for stock issued to investors from the April 2006 private placement in the amount of $308,743 in 2007.

The 2008 revenues and associated expenses were from NIH Grants awarded in September 2004 and September 2006 and from Orphan Australia for NPAP sales of orBec®. The NIH grants support the research and development of our ricin and botulinum vaccines.

For the 12 months ended December 31, 2008, we had revenues of $2,310,265 as compared to $1,258,017 in the 12 months ended December 31, 2007, for an increase of $1,052,248, or 84%. During 2008, we progressed with our September 2006 NIH grant and achieved certain research and development milestones with our subcontractors. In addition, we had revenue of $40,618 from Orphan Australia for NPAP sales of orBec®. We also incurred expenses related to that revenue in the 12 months ended December 31, 2008 and 2007 of $1,886,431 and $943,385, respectively, for an increase of $943,046, or 100%. This difference is in part due to the increased payments made to subcontractors and universities in connection with the grants. Costs of goods associated with NPAP sales of orBec® were $10,551. We also recorded a $100,000 allowance as a reserve for our orBec® inventory.

Our gross profit for the 12 months ended December 31, 2008 was $423,834 as compared to $314,632 in the 12 months ended December 31, 2007, for an increase of $109,202, or 35%. A portion of this difference relates to the aforementioned reclassification of expenses. In the third quarter of 2008, we also capitalized inventory in the net amount of $147,545, as compared to $60,311 in 2007, for certain orBec® costs that were expensed as research and development expenses and, in 2008 we recorded a $100,000 allowance as a reserve for our orBec® inventory.

Research and development spending decreased by $1,547,621, or 50%, to $1,552,323, for the 12 months ended December 31, 2008 as compared to $3,099,944 for the year ended December 31, 2007. During 2008, we incurred expenses for FDA and European regulatory matters, for clinical preparation of orBec® and LPMTM formulation work. The majority of research and development expenses in 2007 were related to FDA and European regulatory matters with respect to the FDA ODAC meeting and the EMEA applications for orBec®, which we did not have in 2008.

General and administrative expenses decreased $922,651, or 32%, to $1,941,719 for the 12 months ended December 31, 2008, as compared to $2,864,370 for the corresponding period ended December 31, 2007. The decrease was primarily due to the dilution expense taken in the first quarter of 2007 for stock issued to investors in the April 2006 private placement in the amount of $308,743. Additionally, the decrease was due to a reduction in employee and consultant expenses, travel expenses and expenses for public and investor relations of approximately $230,000.

Stock based compensation expenses for research and development decreased $48,500, or 21%, to $182,168 for the 12 months ended December 31, 2008, as compared to $230,668 for the corresponding period ended December 31, 2007. The stock based compensation expense for the 12 months ended December 31, 2008 for BioDefense was $92,822 and for BioTherapeutics was $89,346, compared to $69,591 and $161,077, for the corresponding 12 month period in 2007, respectively.

Stock based compensation expenses for general and administrative decreased $243,285, or 54%, to $203,448 for the 12 months ended December 31, 2008, as compared to $446,733 for the corresponding period ended December 31, 2007. This decrease was due to having more initial option grants in 2007 requiring a larger expenditure for the initially vested options.

Interest income for the 12 months ended December 31, 2008 was $37,073 as compared to $164,847 for the 12 months ended December 31, 2007, representing a decrease of $127,774, or 78%. This decrease was due to lower cash balances in 2008 as compared to 2007.

Interest expense for the 12 months ended December 31, 2008 was $3,276 as compared to $1,020 for the 12 months ended December 31, 2007. This increase was the result of higher balances that were short-term financed for insurance premiums due.

We had two active segments for the year ended December 31, 2008 and December 31, 2007: BioDefense and BioTherapeutics. Loss from operations for BioDefense for the 12 months ended December 31, 2008 was $132,272 as compared to $109,698 for the 12 months ended December 31, 2007, representing an increase of $22,574. Loss from operations for BioTherapeutics for the 12 months ended December 31, 2008 was $1,556,429 as compared to $2,748,764 for the 12 months ended December 31, 2007, representing a decrease of $1,192,335. This decrease is primarily attributed to lower research and development costs and lower costs associated with preparation of FDA and European regulatory matters as well as a reduction in general and administrative expenses, such as, public and investor relation expenses, a reduction in employee, travel and consultant expenses, lower expenses for stock based compensation in the amount of $291,785, and the dilution expense taken for stock issued to investors from the April 2006 private placement in the amount of $308,743 in 2007. Loss from operations for Corporate for the 12 months ended December 31, 2008 was $1,767,123 as compared to $3,468,621 for the 12 months ended December 31, 2007, representing a decrease of $1,701,498.

Revenues for BioDefense for the 12 months ended December 31, 2008 were $2,269,647 as compared to $1,258,017 for the 12 months ended December 31, 2007, representing an increase of $1,011,630. During 2008, we progressed with our September 2006 NIH grant and achieved certain research and development milestones with our subcontractors. Revenues for BioTherapeutics for the 12 months ended December 31, 2008 were $40,618 as compared to zero for the 12 months ended December 31, 2007.

Amortization and depreciation expense for BioDefense for the 12 months ended December 31, 2008 was $85,354 as compared to $90,185 for the 12 months ended December 31, 2007, representing a decrease of $4,831. Amortization and depreciation expense for BioTherapeutics for the 12 months ended December 31, 2008 was $58,829 as compared to $24,312 for the 12 months ended December 31, 2007, representing a decrease of $34,517. Amortization and depreciation expense for Corporate for the 12 months ended December 31, 2008 was $5,000 as compared to $5,068 for the 12 months ended December 31, 2007, representing a decrease of $68.

Financial Condition

Cash and Working Capital

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. As of December 31, 2008, we had cash of $1,475,466 as compared to $2,220,128 as of December 31, 2007. As of February 28, 2009, we had cash of approximately $7,100,000. The increase was the result of the sale of our common stock to our commercialization partner Sigma-Tau of $4.5 million and approximately $2.3 million from the sale of our common stock and warrants to accredited investors. As of December 31, 2008, we had working capital of $537,183 as compared to working capital of $1,243,638 as of December 31, 2007, representing a decrease of $706,455. For the 12 months ended December 31, 2008, our cash used in operating activities was approximately $2,800,000, compared to approximately $6,000,000 for the year ended December 31, 2007, reflecting both an increase in grant revenues and reduced costs as we conscientiously slowed our spending in response to difficult conditions in raising funding and progress of our clinical programs. We continue to use equity instruments to provide a portion of the compensation due to our employees, vendors and collaboration partners, and expect to continue to do so in the future.

Based on the our current rate of cash outflows and cash in the bank, we believe that our current cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into the third quarter of 2010. We have approximately $2.0 million in grant funding still available to support our programs in 2009 and beyond. Additionally, we have several grants for several of our programs that have been submitted for government funding.

Management's plan is as follows:

We are exploring out-licensing opportunities for orBec® and oral BDP in territories outside North America, and for LPMTM -Leuprolide and BioDefense programs in the U.S. and in Europe.

We have and will utilize NPAPs wherever possible in countries outside the U.S. to generate revenues from orBec®.

We intend to utilize our existing $8 million equity line of credit with Fusion Capital (approximately $7.8 million of which is still available to us through June 2010) when we deem market conditions to be appropriate.

We expect to receive new government grants intended to support existing and new research and development over the next twelve months. In addition to research and development funding, these grants would provide additional support for our overhead expenditures as well as defray certain costs intended to cover portions of our upcoming confirmatory Phase 3 trial of our lead product orBec®. Therefore these grants would have the effect of extending our cash resources. We routinely file for government grants which support our biotherapeutic and biodefense programs.

We may obtain additional funds through the issuance of equity or equity-linked securities through private placements or rights offerings. We are currently evaluating additional equity financing opportunities and will continue to execute them when appropriate.

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 if 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.

In the event that such growth is less than forecasted in our 2009-2010 operating plan, management has developed contingency plans to reduce operating expenses. However, in any case, there can be no assurance that we will be able to maintain adequate liquidity to allow us to continue to operate the business or prevent the possible impairment of our assets.

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could cause a material adverse effect on our business, operating results, financial condition and prospects.

Since December 31, 2008, we have issued a total of 45,914,035 shares of common stock and warrants to purchase 20,914,035 shares of common stock for gross proceeds of $6,884,200.

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Expenditures

Under our budget and based upon our 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 $6,000,000. 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 $2,000,000, with $600,000 contributing towards our overhead expenses.

The table below details our costs by program for the 12 months ended December 31:

	2008	2007
Program - Research & Development Expenses		
orBec®	$ 921,562	$ 2,288,614
RiVax™	312,486	452,894
BT-VACC™	201,529	315,082
Oraprine™	4,500	5,100
LPMTM-Leuprolide	112,246	38,254
Research & Development Expense	$ 1,552,323	$ 3,099,944
Program - Cost of Goods Sold and Reimbursed under Grants		
orBec®	$ 122,551	$ -
RiVax™	1,681,274	897,470
BT-VACC™	82,606	45,915
Cost of Goods Sold and Reimbursed under Grant	$ 1,886,431	$ 943,385
TOTAL	$ 3,438,754	$ 4,043,329

Debt

We had no debt at December 31, 2008 or at December 31, 2007.

Equity Transactions

On February 11, 2009, in connection with a collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009.

On January 20, 2009, we received $2,384,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreement, we sold 20,914,035 shares at $0.114, together with five year warrants to purchase up to 20,914,035 shares of our common stock at $0.14 per share. The expiration date of the warrants will be accelerated if the Company's common stock meets certain price thresholds, and we would receive additional gross proceeds of approximately $2.9 million if exercised.

During the 12 months ended December 31, 2008, we issued 758,082 shares of common stock as payment to vendors for consulting services. An expense of $111,500 was recorded which approximated the shares' fair market value on the date of issuance, respectively.

During the 12 months ended December 31, 2008, we also issued 993,084 shares of common stock under its existing Fusion Capital Equity facility. The Company received $127,500 in proceeds which approximated the shares' fair market value on the date of issuance.

During the 12 months ended December 31, 2008, we issued 168,309 shares of common stock as compensation and severance for employees. An expense of $26,000 was recorded which approximated the shares' fair market value on the date of issuance, respectively.

On December 1, 2008, we entered into a non-binding letter of intent with 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 pipeline compounds until March 1, 2009. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of our common stock at the market price of $0.09 per share, representing 16,666,667 shares.

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital. The Fusion Capital facility allows us to require Fusion Capital to purchase between $20,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.0 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 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 issued 75,000 shares as a pro rata commitment fee in connection with the purchase of $500,000 of our common stock. If our stock price exceeds $0.15, then the amount required to be purchased 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 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 1,275,000 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 18.5 million shares.

On February 14, 2008, we sold 881,112 shares of our common stock to accredited investors for an aggregate purchase price of approximately $158,600. The investors also received four year warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share.

The total issuance of common stock from private placement for 2008 was 3,658,890 shares; which consisted of the 881,112 shares sold to an institutional investor and other accredited investors for $158,600 and Fusion Capital of

2,777,778 shares for $500,000.

The total issuance of common stock for commitment shares for 2008 was 1,369,125 shares; which were issued to Fusion Capital and consisted of 1,275,000 shares as a commitment fee, 75,000 shares as a commitment fee for the $500,000 invested, and 19,125 shares for the commitment fee on the equity line draws of $127,500.

During 2007 the Company issued 373,607 shares of common stock as part of severance payments to employees. An expense of $85,000 was recorded, which approximated the shares' fair market value on the date of issuance.

For the 12 months ended December 31, 2007, 1,737,200 stock options were exercised to purchase shares of common stock which provided $633,895.

For the 12 months ended December 31, 2007, 6,458,287 common stock warrants were exercised to purchase of common stock which provided $1,592,264.

The total issuance of common stock upon exercise of options and warrants for 2007 was 8,195,487 shares; which consisted of the 1,737,200 stock option exercises and 6,458,287 warrant exercises.

On February 9, 2007, we sold 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. Neither these investors, nor any other investors, 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 which was completed on June 1, 2007.

The total issuance of common stock from private placement for 2007 was 15,745,891 shares; which consisted of the 11,860,850 shares sold to institutional investors and certain of our officers and directors for $5,490,000, less the $254,596 payable as placement agent fees, and 4,065,041 shares to Sigma-Tau for $1,000,000. The total net proceeds from the private placement were $6,235,404.

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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, 2008 or the fiscal year ended December 31, 2007.

Item 8. Financial Statements and Supplementary Data.

See Item 15(a) of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

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Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer, has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Company management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by the Company's Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework.

Based on our assessment, management has concluded that, as of December 31, 2008, the Company's internal control over financial reporting is effective.

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

There were no changes in the Company’s internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the Company’s last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

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.	45	Chairman of the Board
Cyrille F. Buhrman	36	Director
Gregg A. Lapointe, C.P.A., M.B.A.	50	Director
Christopher J. Schaber, Ph.D.	42	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	44	Chief Financial Officer, Senior Vice President, and Director
Brian L. Hamilton, M.D., Ph.D.	61	Chief Medical Officer, and Senior Vice President
Robert N. Brey, Ph.D.	58	Chief Scientific Officer, and Senior Vice President
James Clavijo, C.P.A., M.A.	43	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 Cordex Pharma, Inc. (formerly 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. Dr. Kuo is also a director of Adeona Pharmaceuticals, Inc. (formerly Pipex Pharmaceuticals, Inc.), a public company. After studying molecular biology and receiving his B.A. degree at Haverford College, Dr. Kuo simultaneously received his M.D. degree from The University of Pennsylvania School of Medicine and his M.B.A. degree from The Wharton School of Business at the University of Pennsylvania.

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.

Gregg Lapointe, C.P.A., M.B.A., has been a director since March 10, 2009. Mr. Lapointe also serves on the Board of Directors of the Pharmaceuticals Research and Manufacturers of America (PhRMA) and is a member of the Corporate Council of the National Organization for Rare Diseases (NORD). He has served in varying roles for Sigma-Tau, a private biopharmaceutical company, since September 2001, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer since April 2008. From May, 1996 to August, 2001, he served as Vice President of Operations and Vice President, Controller of AstenJohnson, Inc. (formerly JWI Inc.). Prior to that Mr. Lapointe spent several years in the Canadian medical products industry in both distribution and manufacturing. Mr. Lapointe began his career at Price Waterhouse. From his extensive background, Mr. Lapointe has significant experience in the areas of global strategic planning and implementation, business development, corporate finance, and acquisitions. Mr. Lapointe received his B.A. degree in Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill University and his M.B.A. degree from Duke University. He is a C.P.A. in the state of Illinois and a Chartered Accountant in Ontario, Canada.

Christopher J. Schaber, Ph.D., has been our President and Chief Executive Officer and a director since August 2006. Dr. Schaber also currently serves on the boards of both the Alliance for BioSecurity and BioNJ, Inc. Prior to joining DOR, 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. degree from Western Maryland College, his M.S. degree in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. degree in Pharmaceutical Sciences from The Union Graduate School.

Evan Myrianthopoulos has been a director since 2002 and is currently our Chief Financial Officer and Senior Vice President, 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. degree in Economics and Psychology from Emory University.

Brian L. Hamilton, M.D., Ph.D., has been Chief Medical Officer and Senior Vice President since March 11, 2009. His academic career at the University of Washington and the University of Miami focused on the use of bone marrow transplantation to treat children with congenital immune deficiency, with research in the immunobiology of GVHD. In the pharmaceutical industry, he has worked with both large pharmaceutical companies (Astra, USA and Wyeth) and several biotechnology companies. From December 2001 to June 2004, he was Senior Director of Clinical Research with Wyeth Research. From June 2004 to March 2006, he was Vice President for Clinical and Regulatory Affairs at Merrimack Pharmaceutical. He was Chief Medical Officer with BioVex from September 2006 to March 2007. He was a consultant in clinical development as Medical Director with Biopharm Solutions, Inc. from March 2007 to October 2008. From October 2008 to March 2009, he was Acting Vice President of Medical Affairs with Ziopharm Oncology. He has expertise in clinical development and regulatory affairs with small molecules, biologics, vaccines, and genetically modified oncolytic viruses in oncology, hematology, rheumatology, and immunology. At Astra, USA, he had a significant role in the clinical development and registration of both Pulmicort Turbuhaler for the treatment of patients with asthma and Rhinocort Aqua for the treatment of patients with allergic rhinitis. Dr. Hamilton received his M.D. and Ph.D. degrees from the University of Washington, with post-graduate training in Pediatrics, Allergy, Immunology, and Oncology.

Robert N. Brey, Ph.D., has been with the Company since January 1996, and is currently our Chief Scientific Officer and Senior Vice President. He has also held the positions of Vice President Vaccine Development and Vice President of Research and Development. He also has held Scientific, Management and Project Management positions in the Lederle-Praxis division of American Cyanamid, now a division of Wyeth, in which he participated in the successful development a of a vaccine for Haemophilius influenzae meningitis, and a vaccine for pneumonia. While at Lederle-Praxis, Dr. Brey was Manager of Molecular Biology Research for vaccines and Project Manager for development of oral vaccines from 1985 through 1993. From 1993 through 1994, Dr. Brey served as Director of Research and Development of Vaxcel, in which he was responsible for developing adjuvant technology and formulations for improved vaccines. From 1994 through 1996, Dr. Brey established an independent consulting group, Vaccine Design Group, to identify and develop novel vaccine technologies and platforms. Before entering into drug and vaccine delivery, he held senior scientific positions at Genex Corporation from 1982 through 1986. Dr. Brey received a B.S. degree in Biology from Trinity College in Hartford, Connecticut, his Ph.D. degree in Microbiology from the University of Virginia and performed postdoctoral studies at MIT with Nobel Laureate Salvador Luria.

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. degree in Accounting from Florida International University, a B.A. degree in Accounting from the University of Nebraska, and a B.S. degree in Chemistry from the University of Florida. Mr. Clavijo is a licensed Certified Public Accountant in the state of Florida.

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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, 2008, our officers, directors and significant stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act..

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 independent directors Dr. Kuo, Mr. Buhrman and Mr. Lapointe. Mr. Lapointe was appointed on March 27, 2009. The board of directors has determined that each of Dr. Kuo, Mr. Buhrman and Mr. Lapointe 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 11. Executive Compensation.

Summary Compensation

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2008 and 2007 to the persons who served as our Chief Executive Officer, and each of the two other most highly compensated executive officers during 2008 (collectively, the "Named Executive Officers").

Summary Compensation Table

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber (1)	C.E.O. & President	2007	$300,000	$100,000	$155,409	$47,798	$603,207
		2008	$300,000	$100,000	$185,721	$24,844	$610,565
Evan Myrianthopoulos (2)	C.F.O. & Sr. V.P.	2007	$200,000	$ 50,000	$146,938	$44,786	$441,724
		2008	$200,000	$ 50,000	$ 66,033	$23,474	$339,507
Robert N. Brey (3)	C.S.O. & Sr. V.P.	2007	$190,000	$ 15,000	$ 48,252	$18,325	$271,577
		2008	$190,000	$ 20,000	$ 55,133	$18,405	$283,538

(1) Dr. Schaber deferred payment of his 2008 annual bonus of $100,000 until February 28, 2009. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2008 includes $24,844 for insurance costs. Other Compensation for 2007 includes $19,000 for insurance costs, $2,301 for transportation costs, $7,263 for travel expenses and $19,234 for lodging costs.

(2) Mr. Myrianthopoulos deferred payment of his 2008 annual bonus of $50,000 until February 28, 2009. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2008 includes $23,474 for insurance costs. Other Compensation for 2007 includes $17,000 for insurance costs, $2,895 for transportation costs, $6,787 for travel expenses and $18,104 for lodging costs.

(1) Dr. Brey deferred payment of his 2008 annual bonus of $20,000 until January 31, 2009. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2008 includes $18,405 for insurance costs. Other Compensation for 2007 includes $18,325 for insurance costs.

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 to 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. This employment agreement was renewed in December 27, 2007 for a term of three years. 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.

Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) 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 remainder of their term and become the property of Dr. Schaber's immediate family.

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. This employment agreement was renewed in December 27, 2007 for a term of three years. 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.

Mr. Myrianthopoulos' monetary compensation (base salary of $200,000 and bonus of $50,000) 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 remainder of their term and become property of Mr. Myrianthopoulos' immediate family.

On March 27, 2009, the Compensation Committee approved the increase in salaries for: Dr. Schaber to $350,000; Mr. Myrianthopoulos to $230,000; and Dr. Brey to $200,000. Dr. Brey does not have an employment agreement.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber, Mr. Myrianthopoulos and Dr. Brey 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 200,000 common shares to Dr. Brey. The amended agreements include our obligation to issue such shares to the executives if

such event occurs.

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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 outstanding at December 31, 2008. 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	2,083,343	416,657	416,657	$0.27	8/28/2016
	506,250	393,750	393,750	$0.47	8/29/2017
	700,000	2,100,000	2,100,000	$0.06	12/17/2018
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
	375,000	25,000	25,000	$0.35	5/10/2016
	309,375	240,625	240,625	$0.47	8/29/2017
	300,000	900,000	900,000	$0.06	12/17/2018
Robert N. Brey	10,000	-	-	$2.00	2/23/2009
	9,000	-	-	$3.94	2/08/2010
	562,500	37,500	37,500	$0.33	5/10/2016
		75,000	75,000	$0.47	8/29/2017

	125,000				
	200,000	600,000	600,000	$0.06	12/17/2018

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Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2008.

Director Compensation

Name	Fees Earned of Paid in Cash ($) (1)	Option Awards ($) (2)	Total ($)
James S. Kuo	$16,000	$-	$16,000
Cyrille F. Buhrman	$9,000	$-	$9,000

(1) Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent 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 or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 300,000 shares of common stock, and subsequent prorated annual grants of fully vested options to purchase 150,000 shares of common stock after re-election to our Board of Directors. During 2008, we did not hold an annual meeting. As a result there were no stock options granted to the Board of Directors in 2008. Option Awards include the value of stock option awards of vested shares of Common Stock as required by FASB No. 123R.

Item 12. 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 25, 2009 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
Sigma-Tau Pharmaceuticals, Inc. (1)	41,666,667	25.0%
Biotex Pharmaceuticals, LLC (2)	40,000,000	21.4%
Cyrille F. Buhrman (3)	5,125,020	3.1%
Christopher J. Schaber (4)	4,108,749	2.4%
Evan Myrianthopoulos (5)	2,368,125	1.4%
Robert N. Brey (6)	1,019,000	*
James Clavijo (7)	950,691	*
James S. Kuo (8)	630,000	*
Gregg A. Lapointe (9)	300,000	*
Brian L. Hamilton (10)	250,000	*
All directors and executive officers as a group (8 persons)	14,751,585	8.8%

* 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 25, 2009 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 167,070,944 shares of common stock outstanding as of March 25, 2009.

(1) Includes 41,666,667 shares of common stock. The amount does not include 1,546,870 shares of common stock held by Paolo Cavazza, one of the principal owners of Sigma-Tau. The address of Sigma-Tau Pharmaceuticals, Inc. is c/o Sigma-Tau Pharmaceuticals, Inc., 800 South Frederick Avenue, Suite 300, Gaithersburg, Maryland 20877.

(2) Includes 20,000,000 shares of common stock and warrants to purchase 20,000,000 shares of common stock within 60 days of March 25, 2009. The address of Biotex Pharma Investments, LLC is c/o Biotex Pharma Investments, LLC, 220 West 42nd Street 6th Floor New York, NY 10036.

(3) Includes 4,900,020 shares of common stock and options to purchase 225,000 shares of common stock within 60 days of March 25, 2009. The address of Mr. Buhrman is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(4) Includes 392,766 shares of common stock owned by Dr. Schaber and options to purchase 3,715,983 shares of common stock within 60 days of March 25, 2009. The address of Dr. Schaber is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(5) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 2,053,125 shares of common stock and warrants to purchase 90,220 shares of common stock within 60 days of March 25, 2009. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(6) Includes options to purchase 1,019,000 shares of common stock within 60 days of March 25, 2009. The address of Dr. Brey is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(7) Includes 88,191 shares of common stock owned by Mr. Clavijo and options to purchase 862,500 shares of common stock within 60 days of March 25, 2009. The address of Mr. Clavijo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(8) 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 25, 2009. The address of Dr. Kuo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(9) Includes options to purchase 300,000 shares of common stock within 60 days of March 25, 2009. The address of Mr. Lapointe is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(10) Includes options to purchase 250,000 shares of common stock within 60 days of March 25, 2009. The address of Dr. Hamilton 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, 2008, 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)	16,370,039	$ 0.27	3,547,331
Equity compensation plans not approved by security holders	-	-	-
TOTAL	16,370,039	$0.27	3,547,331

(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 1,482,669 shares to individuals as payment for services in the amount of $380,342 as allowed in the plan.

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Item 13. Certain Relationships and Related Transactions and Director Independence.

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, 2008. For a discussion of our employment agreements and compensation paid to our directors, see “Item 11. Executive Compensation.”

Director Independence

The Board of Directors has determined that Cyrille F. Buhrman and James S. Kuo are "independent" as such term is defined by the applicable listing standards of American Stock Exchange. Our Board of Directors based this determination primarily on a review of the responses of the Directors to questionnaires regarding their employment, affiliations and family and other relationships.

Item 14. Principal Accountant Fees and Services

December 31,		
	2008	2
	$107,302	$8
d	6,254	
	9,229	1
	$122,785	$9

The preceding table highlights the aggregate fees billed during the years ended December 31, 2008 and 2007 by Sweeney, Matz & Co., LLC, our principal accountants in 2008 and 2007 for services performed during the audit for each of those years and reviews of our financial statements included in our Quarterly Reports on Form 10-Q during those fiscal years. Although Amper was engaged for the December 31, 2008 audit our fees related to them will be incurred in 2009.

Audit Related Fees

The aggregate fees billed for audit related fees such as registration statements and related services during the years ended December 31, 2008 and 2007 were $6,254 and $4,000, respectively.

Tax Fees

Sweeney, Matz & Co., LLC billed us $9,229 and $10,202 for tax compliance for the year ended December 31, 2008 and 2007, respectively. We have engaged Gentile, Pismeny & Brengel, LLP as our new tax advisors. Our fees associated with our 2008 tax returns will be incurred in 2009.

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, 2008 and 2007.

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.

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Part IV

Item 15. Exhibits, Financial Statements and Schedules.

The following financial statements and exhibits are filed as part of this Annual Report beginning on page 42:

(a) Financial Statements:

(i) Reports of Independent Registered Public Accounting Firm.

(ii) Consolidated Balance Sheets as of December 31, 2008 and 2007.

(iii) Consolidated Statements of Operations for the years ended December 31, 2008 and 2007.

(iv) Consolidated Statements of Stockholders' Deficiency for the years December 31, 2008 and 2007.

(v) Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007.

(vi) Notes to Consolidated Financial Statements.

(b) 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 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).

4.2 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).

4.3 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).

4.4 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).

4.5 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).

4.6 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).

4.7 Form of Warrant issued to each investor in the February 2008 private placement (incorporated by reference to Exhibit 10.2 in our current report on Form 8-K filed on January 21, 2009).

4.8 Form of Warrant issued to each investor in the January 2009 private placement (incorporated by reference to Exhibit 4.18 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

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 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).

10.3 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).

10.4 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).**

10.5 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).**

10.6 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).

10.7 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).

10.8 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).

10.9 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).

10.10 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).

10.11 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).**

10.12 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).**

10.13 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).**

10.14 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).

10.15 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).

10.16 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).

10.17 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005).**

10.18 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).

10.19 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)

10.20 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).

10.21 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).

10.22 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).

10.23 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).**

10.24 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).

10.25 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).

10.26 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).

10.27 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).

10.28 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).

10.29 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).

10.30 Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company.* **

10.31 Employment Agreement dated December 27, 2007, between Evan Myrianthopoulos and the Company.* **

10.32 Employment Agreement dated December 27, 2007, between James Clavijo, CPA and the Company.* **

10.33 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 on Form S-1 filed on February 14, 2008).

10.34 Registration Rights 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) on Form S-1 filed on February 14, 2008).

10.35 Letter dated December 1, 2008, 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 December 1, 2008).

10.36 Form of Securities Purchase Agreement between the Company and each investor dated February 14, 2008 (incorporated by reference to Exhibit 10.37 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

10.37 Common Stock Purchase Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 21, 2009).

10.38 Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21, 2009).

10.39 Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21,
10.40 2009).

10.41 Exclusive License Agreement dated November 24, 1998, between Enteron Pharmaceuticals, Inc. and George B. McDonald, M.D. and amendments (incorporated by reference to Exhibit 10.42 included on Form S-1 filed on
10.42 February 13, 2009).

Collaboration and Supply Agreement dated February 11, 2009, between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.43 included on Form S-1 filed on February 13, 2009).

Common Stock Purchase Agreement dated February 11, 2009, between the Company and Sigma Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.44 included on Form S-1 filed on February 13, 2009).

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 Certiifcation of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002. *

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

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* Filed herewith

** Indicates management contract or compensatory plan.

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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 sheet of DOR BioPharma, Inc. and subsidiaries as of December 31, 2007 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2007. 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 audit in accordance with standards of the Public Company Accounting Oversight Board (U.S.). Those standards require that we plan and perform the audit 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 audit provides 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 the results of its operations and its cash flows for the year ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

/s/ Sweeney, Matz & Co., LLC

Fort Lauderdale, Florida
March 8, 2008

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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 sheet of DOR BioPharma, Inc. and subsidiaries as of December 31, 2008 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2008. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropri−ate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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, 2008, and the results of its operations and its cash flows for the year ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey
March 27, 2009

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DOR BioPharma, Inc.
Consolidated Balance Sheets
December 31,

	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 1,475,466	$ 2,220,128
Grants receivable	278,316	97,845
Inventory, net	82,182	-
Prepaid expenses	86,837	119,178
Total current assets	1,922,801	2,437,151
Office and laboratory equipment, net	21,217	25,941
Intangible assets, net	1,418,717	1,320,787
Total assets	$ 3,362,735	$ 3,783,879
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,015,005	$ 847,610
Accrued compensation	370,614	345,903
Total current liabilities	1,385,619	1,193,513
Commitments and contingencies		
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 118,610,704 and 94,996,547, respectively issued and outstanding	118,610	94,996
Additional paid-in capital	104,176,253	101,391,090
	( )	)
Accumulated deficit	102,317,747	(98,895,720
Total shareholders' equity	1,977,116	2,590,366
Total liabilities and shareholders' equity	$ 3,362,735	$ 3,783,879

The accompanying notes are an integral part of these financial statements

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

	2008	2007
Revenues	$ 2,310,265	$ 1,258,017
Cost of revenues	(1,886,431)	(943,385)
Gross profit	423,834	314,632
Operating expenses:		
Research and development	1,552,323	3,099,944
General and administrative	1,941,719	2,864,370
Stock based compensation research and development	182,168	230,668
Stock based compensation general and administrative	203,448	446,733
Total operating expenses	3,879,658	6,641,715
Loss from operations	(3,455,824)	(6,327,083)
Other income (expense):		
Interest income	37,073	164,847
Interest (expense)	(3,276)	(1,020)
Other (expense)	-	(1,387)
Total other income (expense)	33,797	162,440
Net loss	$ (3,422,027)	$ (6,164,643)
BasicnBasic and diluted net loss per share	$ (0.03)	$ (0.07)
Basic Basic and diluted weighted average common shares outstanding	101,881,991	90,687,677

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2008 and 2007

	Common Stock		Additional Paid-In capital	Accumulated Deficit
	Shares	Par Value		
Balance, January 1, 2007	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 upon 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 common stock to investors by contract as dilution protection	995,947	996	307,747	-
Issuance of common stock as payment 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)
Issuance of common stock from private placement	3,658,890	3,659	654,940	-
Issuance of common stock for	1,369,125	1,369	(1,369)	-

commitment shares				
Issuance of common stock for execution of letter of intent	16,666,667	16,667	1,483,333	-
Issuance of common stock for equity line	993,084	993	126,507	-
Issuance of common stock to vendors	758,082	758	110,440	-
Issuance of common stock as payment to employees	168,309	168	25,696	-
Stock option expense	-	-	385,616	-
Net loss	-	-	-	(3,422,027)
Balance, December 31, 2008	118,610,704	$118,610	$104,176,253	($102,317,747)

The accompanying notes are an integral part of these financial statements

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

	2008	2007
Operating activities		
Net loss	$ (3,422,027)	$ (6,164,643)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	149,183	119,565
Inventory reserve	100,000	-
Non-cash stock compensation	522,678	1,401,777
Change in operating assets and liabilities:		
Grants receivable	(180,471)	(7,912)
Inventory	(182,182)	-
Prepaid expenses	32,341	(24,708)
Accounts payable	167,396	(1,264,868)
Accrued compensation	24,710	(57,044)
Total adjustments	633,655	166,810
Net cash used by operating activities	(2,788,372)	(5,997,833)
Investing activities:		
Purchases of office and laboratory equipment	(5,277)	(7,170)
Acquisition of intangible assets	(237,113)	(356,192)
Net cash used by investing activities	(242,390)	(363,362)
Financing activities:		
Net proceeds from issuance of common stock	2,158,600	6,235,404
Proceeds from equity line	127,500	-
Proceeds from exercise of warrants	-	1,592,263
Proceeds from exercise of stock options	-	634,020
Net cash provided by financing activities	2,286,100	8,461,687
Net increase (decrease) in cash and cash equivalents	(744,662)	2,100,492
Cash and cash equivalents at beginning of period	2,220,128	119,636
Cash and cash equivalents at end of period	$ 1,475,466	$ 2,220,128
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 3,276	$ 1,020
Non-cash transactions:		
Issuance of commitment shares	$ 272,484	$ -
Issuance of shares for anti-dilution	$ -	$ 308,743

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

Basus of Presentations

The Company is a late stage biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic products and biodefense vaccines intended for areas of unmet medical need. DOR's biotherapeutic business segment intends to develop orBec®, oral BDP, and other biotherapeutic products namely LPMTM-Leuprolide. DOR's biodefense business segment intends to convert its ricin toxin, botulinum toxin, and anthrax vaccine programs from early stage development to advanced development and manufacturing.

During the 12 months ended December 31, 2008, the Company had two customers, the U.S. Federal Government and Orphan Australia Pty Ltd. ("Orphan Australia"), a specialty pharmaceutical company based in Melbourne, Australia, through a Named Patient Access Program ("NPAP") for orBec®. Revenues from the U.S. Federal Government were generated from three active grants. As of December 31, 2008 outstanding receivables were from the U.S. Federal Government, the National Institutes of Health and The U.S. Food and Drug Administration and Orphan Australia.

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.

Liquidity

As of December 31, 2008, the Company had cash of $1,475,466 as compared to $2,220,128 as of December 31, 2007. As of December 31, 2008, the Company had working capital of $537,183 as compared to working capital of $1,243,638 as of December 31, 2007, representing a decrease of $706,455.

As of February 28, 2009, the Company had cash of approximately $7,100,000. The increase was the result of the sale of the Company's common stock to its commercialization partner Sigma-Tau of $4.5 million and $2.3 million from the sale of the Company's common stock to accredited investors. For the 12 months ended December 31, 2008, the Company's cash used in operating activities was approximately $2,800,000, compared to $6,000,000 for the corresponding period ended December 31, 2007, reflecting both an increase in grant revenues and reduced costs as the Company conscientiously slowed its spending in response to difficult conditions in raising funding and regulatory progress. The Company continues to use equity instruments to provide a portion of the compensation due to employees, vendors and collaboration partners, and expect to continue to do some in the future.

Based on the Company's current rate of cash outflows and cash in the bank, the Company believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the third quarter of 2010. The Company has $2.0 million in grant funding still available to support its programs in 2009 and beyond. Additionally, the Company has several grants for several of its programs that have been submitted for government funding.

Management's plan is as follows:

> The Company is exploring out-licensing opportunities for orBec® and oral BDP in territories outside North America, and for LPMTM-Leuprolide and BioDefense programs in the United States and in Europe.

The Company has and will utilize NPAPs wherever possible in countries outside the United States to generate revenues from orBec®.

The Company intends to utilize its existing $8 million equity line of credit with Fusion Capital (approximately $7.8 million of which is still available to the Company through June 2010) when it deems market conditions to be appropriate.

The Company expects to receive new government grants intended to support existing and new research and development over the next twelve months. In addition to research and development funding, these grants would provide additional support for its overhead expenditures as well as defray certain costs intended to cover portions of its upcoming confirmatory Phase 3 trial of its lead product orBec®. Therefore these grants would have the effect of extending its cash resources. The Company routinely files for government grants which support its biotherapeutic and biodefense programs.

The Company may obtain additional funds through the issuance of equity or equity-linked securities through private placements or rights offferings. The Company is currently evaluating additional equity financings opportunities and will continue to execute them when appropriate.

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.

In the event that such growth is less than forecasted in our 2009-2010 operating plan, management has developed contingency plans to reduce the Company operating expenses. However, in any case, there can be no assurance that the Company will be able to maintain adequate liquidity to allow the Company to continue to operate its business or prevent the possible impairment of its assets.

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2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma, Inc., and its wholly and majority owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated as a result of 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 National Institute of Health of the U.S. Federal Government for costs incurred prior to the period. The amounts were billed in the month subsequent to period end and collected shortly thereafter. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Intangible Assets

One of the most significant estimates or judgments that the Company makes 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.

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 component 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.

The Company capitalized $237,113 and $356,192 in patent related costs during the year ended December 31, 2008 and the year ended December 31, 2007, respectively. These amounts are represented in the cash flow statements, in the section for investing activities presented in the financial statements. On the balance sheet as of December 31, 2008 and December 31, 2007, these amounts are presented on the line intangible assets, net in the amount of $1,418,717 and $1,320,787, respectively.

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 did not record an impairment of intangible assets for the 12 months ended December 31, 2008 or 2007.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out ("FIFO") method and includes the cost of materials and overhead. The Company records an allowance as needed for excess inventory. For the three months ended December 31, 2008 an allowance of $100,000 was provided. This allowance will be evaluated on a quarterly basis and adjustments will be made as required. All inventory for this period is finished goods and consists of orBec® treatments.

Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. 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

The Company's revenues are from government grants and NPAP sales of orBec® from Orphan Australia. The revenue from government grants are based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, 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. The revenues from the NPAP sales of orBec® are recognized when the product is shipped. NPAP sales are FOB shipping.

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.

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Stock Based Compensation

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 115% and 99% in 2008 and 2007, respectively, and average risk-free interest rates of 1.1% and 4.5% in 2008 and 2007, respectively. The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant at the 12 months ended December 31, 2008 and December 31, 2007 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. The Company awarded 6,800,000 stock options for the 12 months ended December 31, 2008 while 3,375,000 stock options were granted during the 12 months ended December 31, 2007. The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.06, and $0.27 for the 12 months ended December 31, 2008 and 2007, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123R 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. The option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. Upon exercise, shares are issued from the amended 2005 equity incentive plan and increase the number of shares the Company has outstanding.

Income Taxes

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, 2008 due to the net operating losses incurred by the Company since its inception. Additionally, the Company has not recorded a liability for unrecognized tax benefits for December 31, 2008 and 2007.

Basic earnings per share

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a large number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

A reconciliation of the applicable numerators and denominators of the income statement periods presented is as follows (millions, except earnings per share amounts):

	Year Ended	Year Ended

	December 31, 2008			December 31, 2007		
	Loss	Shares	EPS	Loss	Shares	EPS
Basic EPS Dilutives:	($3.42)	101.88	($0.03)	($6.16)	90.69	($0.07)
Options and Warrants	-	-	-	-	-	-
Diluted EPS	($3.42)	101.88	($0.03)	($6.16)	90.69	($0.07)

Options and warrants outstanding at December 31, 2008 and 2007 were 16,370,039 and 10,349,839 options, and 20,350,148 and 29,209,341 warrants, respectively. No options and warrants were included in the 2008 and 2007 computations of diluted earnings because the effect would be anti-dilutive due to losses in the respective years.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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 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. In January 2008 the Company adopted SFAS 159 to determine the fair value on its financial assets and financial liabilities. This adoption had no material impact on the Company’s consolidated financial position, results of operations or cash flows.

EITF 07-05, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock,” addresses the first part of paragraph 11A of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities,” as to whether or not a derivative is indexed to an entity’s own stock. EITF 07-05 will require many awards to be accounted for as liabilities under SFAS No. 133 that may have previously been accounted for as equity. EITF 07-05 becomes effective for fiscal years, including those interim periods, beginning after December 15, 2008. The EITF is thus applicable starting January 1, 2009, for the Company. The EITF is applicable to all instruments outstanding at the beginning of the period of adoption. The Company is currently evaluating the applicability of the guidance in EITF 07-05 and analyzing the impact on its financial statements.

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 will adopt SFAS 141(R) in conjunction with SFAS No. 160

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. The adoption of this standard is not expected to have a significant impact on the Company’s consolidated financial position, results of operations or cash flows.

In January 2008, the Company adopted the provisions of SFAS No. 157, “Fair Value Measurements,” for financial assets and financial liabilities. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The company will

delay the application of SFAS 157 for non-financial assets and non-financial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), in accordance with Financial Accounting Standards Board Staff Position (FSP) No. SFAS 157-2, “Effective Date of FASB Statement No. 157,” until January 2009.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles". SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS No. 162 became effective in September 2008. The adoption of this statement did not have a material effect on the Company's financial statements.

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3. Office and Laboratory Equipment

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

	2008	2007
Office equipment	$ 130,605	$ 125,328
Laboratory equipment	23,212	23,212
Total	153,817	148,540
Accumulated depreciation	(132,600)	(122,599)
	$ 21,217	$ 25,941

Depreciation expense was $10,001 and $10,781 for the years ended December 31, 2008 and 2007.

4. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2008				
Licenses	11.7	$ 462,234	$ 142,994	$ 319,240
Patents	9.0	1,870,603	771,126	1,099,477
Total	9.5	$ 2,332,837	$ 914,120	$ 1,418,717
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

Amortization expense was $139,183 in 2008 compared to $108,784 for 2007.

Based on the balance of licenses and patents at December 31, 2008, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2009	$ 150,000
2010	151,000
2011	152,000
2012	153,000
2013	154,000

License fees and royalty payments are expensed annually as incurred as the Company does not attribute any future benefits other than within that period.

5. Inventory

In the third quarter of 2008, the Company purchased and recorded inventory for the first time, because of the development of the NPAP programs which provided the Company the ability to sell orBec® for the first

time. Inventory consists of finished goods. For the 12 month period ended December 31, 2008 the Company also recorded an allowance for excess inventory of $100,000.

6. Income Taxes

Deferred tax assets as of December 31:

	2008	2007
Deferred tax assets:		
Net operating loss carry forwards	$ 26,300,000	$25,000,000
Orphan drug and research and development credit carry forwards	2,000,000	2,000,000
Other	3,300,000	3,000,000
Total	31,600,000	30,000,000
Valuation allowance	(31,600,000)	(30,000,000)
Net deferred tax assets	$ -	$ -

At December 31, 2008, the Company had net operating loss carry forwards of approximately $76,000,000 for Federal and state tax purposes, portions of which are currently expiring each year until 2028. In addition, the Company had $2,000,000 of various tax credits that start expiring from December 2009 to December 2028. The Company may be able to utilize their NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is possible that the utilization of the NOLs may be limited.

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 and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The net change in the valuation allowance for the year ended December 31, 2008 and December 31, 2007 was an increase of approximately $1,600,000 and decrease of $1,000,000 respectively, resulting primarily from net operating losses generated. As a result of the Company’s continuing tax losses, the Company has recorded a full valuation allowance against a net differed tax asset.

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, 2008 and 2007 was as follows:

	2008	2007
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(6.50)	(4.29)
Valuation allowance	40.50	38.29
Provision for income taxes (benefit)	- %	- %

Effective January 1, 2007, the Company adopted Financial Interpretation ("FIN") No. 48, Accounting for Uncertainty in Income Taxes – An Interpretation of FASB Statement No. 109. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The adoption did not have an effect on the consolidated financial statements.

7. Shareholders' Equity

Preferred Stock

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

Common Stock

During the 12 months ended December 31, 2008, the Company issued 758,082 shares of common stock as payment to vendors for consulting services. An expense of $111,500 was recorded which approximated the shares' fair market value on the date of issuance, respectively.

During the 12 months ended December 31, 2008 the Company also issued 993,084 shares of common stock under its existing Fusion Capital Equity facility. The Company received $127,500 in proceeds which approximated the shares' fair market value on the date of issuance.

During the 12 months ended December 31, 2008, the Company issued 168,309 shares of common stock as compensation and severance for employees. An expense of $26,000 was recorded which approximated the shares' fair market value on the date of issuance.

On December 1, 2008, the Company entered into a non-binding letter of intent with 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 pipeline compounds until March 1, 2009. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of the Company's common stock at the then market price of $0.09 per share, representing 16,666,667 shares.

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 the Company to require Fusion Capital to purchase between $20,000 and $1.0 million every two business days, of the Company's common stock up to an aggregate of $8.0 million over approximately a 25-month period depending on certain conditions including the quoted market price of the Company's common stock on such date. 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 made an initial purchase of 2,777,778 common shares and received 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. The Company issued an additional 75,000 shares of common stock as a commitment fee in connection with this $500,000 purchase. If the Company's stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of the Company's common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company's common stock on any trading days that the market price of the Company's common stock is less than $0.10 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 1,275,000 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 18.5 million shares.

On February 14, 2008, the Company sold 881,112 shares of its common stock to an institutional and other accredited investors for an aggregate purchase price of approximately $158,600. The investors received four year warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share.

The total issuance of common stock from private placement for 2008 was 3,658,890; which consisted of the 881,112 sold to an institutional investor and other accredited investors for $158,600 and Fusion Capital of 2,777,778 for $500,000.

The total issuance of common stock for commitment shares for 2008 was 1,369,125; which were issued to Fusion Capital and consisted of 1,275,000 as a commitment fee, 75,000 as a commitment fee for the $500,000 invested, and 19,125 for the commitment fee shares on the equity line draws of $127,500.

During the year ended December 31, 2007, the Company issued 829,821 shares of common stock as payment to vendors for consulting services. An expense of $330,500 was recorded, which approximated the shares' fair market value on the date of issuance.

During 2007 the Company issued 373,607 shares of common stock as part of severance payments to employees. An expense of $85,000 was recorded, which approximated the shares' fair market value on the date of issuance.

For the 12 months ended December 31, 2007, 1,737,200 stock options were exercised to purchase shares of common stock which provided $633,895.

For the 12 months ended December 31, 2007, 6,458,287 common stock warrants were exercised to purchase of common stock which provided $1,592,264.

The total issuance of common stock upon exercise of options and warrants for 2007 was 8,195,487; which consisted of the 1,737,000 stock option exercises and 6,458,287 warrant exercises.

On February 9, 2007, the Company sold 11,680,850 shares of its 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 995,947 shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock and the Company recorded dilution expense of $308,743. Additionally. 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. Neither 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 and on June 1, 2007, the Company returned the $2 million to Sigma-Tau.

The total issuance of common stock from private placement for 2007 was 15,745,891; which consisted of the 11,860,850 sold to institutional investors and certain Company's officers and directors for $5,490,000 less the $254,596 payable as placement agent fees, and to 4,065,041 to Sigma-Tau for $1,000,000.

8. 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 issued common stock or 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,	2008	2007
Shares available for grant at beginning of year	10,612,961	3,236,032
Increase in shares available	-	10,000,000
Options granted	(6,800,000)	(3,375,000)
Options forfeited or expired	100,000	1,140,000
Common stock payment for services	(365,630)	(388,071)
Shares available for grant at end of year	3,547,331	10,612,961

The Amended and Restated 1995 Omnibus 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 2008 there were no stock option exercises. In 2007, 1,487,200 stock options were exercised under the 1995 plan and 250,000 stock options were exercised under the 2005 plan, for a total of 1,737,200 stock option exercises.

The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2008 and 2007 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at January 1, 2007	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
Granted	6,800,000	0.06
Forfeited	(779,800)	0.81
Balance at December 31, 2008	16,370,039	$ 0.27

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The weighted-average exercise price, by price range, for outstanding options at December 31, 2008 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.06-$0.20	9.8	6,950,000	1,887,500
$0.22-$0.49	7.3	8,770,000	7,155,935
$0.50-$4.00	2.9	650,039	650,039
Total	8.2	16,370,039	9,693,474
Intrinsic Value	-	-	

Stock options are issued at the market price on the date of issuance. Stock options issued to directors are fully vested upon issuance. Stock options issued to employees generally vest 25% upfront, then 25% each year for a period of three years. Stock options vest 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 six months.

The intrinsic value was calculated as the difference between the Company's common stock closing price on the OTC BB at December 31, 2008 and the exercise price of the stock option issued multiplied by the number of stock options. The Company's common stock price at December 31, 2008 was $0.06.

The Company's share-based compensation for the 12 months ended December 31, 2008 and 2007 was $385,616 and $677,401 respectively. For the 12 months ended December 31, 2008, $182,168 of the $385,616 was for Research and Development personnel and $203,448 was for General and Administrative personnel. For the same period in 2007, $230,668 of the $677,401 was for Research and Development personnel and $446,733 was for General and Administrative personnel. At December 31, 2008, the total compensation cost for stock options not yet recognized was approximately $490,000 and will be expensed over the next three years.

From time to time, the Company grants warrants to consultants and grants warrants to purchase common stock in connection with private placements. Warrants issued to consultants during 2008 and 2007 were 250,000 and zero shares, respectively, and resulted in expense charges of $21,000 and zero, respectively.

Warrants to purchase common stock

Warrant activity for the years ended December 31, 2008 and 2007 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at January 1, 2007	37,128,790	$ 0.65
Granted	560,106	0.59
Expired	(2,021,268)	1.93
Exercised	(6,458,287)	0.25
Balance at December 31, 2007	29,209,341	0.69
Granted	2,079,444	0.20
Expired	(10,938,637)	1.13
Balance at December 31, 2008	20,350,148	$ 0.41

During 2009, warrants to purchase approximately 10,500,000 of the Company's common stock will expire.

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2008 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.06-$0.25	0.8	10,120,330	10,120,330
$0.26-$0.51	1.6	6,359,575	6,359,575
$0.52-$0.88	1.2	3,870,243	3,870,243
Total	1.1	20,350,148	20,350,148

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9. Concentrations

At December 31, 2008 and 2007, the Company had deposits in financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation ("SIPC"). Currently we are covered by $1,000,000 by the SIPC. The excess amounts at December 31, 2008 and December 31, 2007 were approximately, $475,000 and $1,200,000, respectively. These funds are held at a major Banking Institution.

10. Commitments and Contingencies

The Company has commitments of approximately $5.6 million at December 31, 2008 in connection with a collaboration agreement with Numoda for the execution of our upcoming confirmatory, Phase 3 clinical trial of orBec® that will began in November 2008 and is expected to continue through November 2010.

The Company has several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

Certain operating leases for office and warehouse space maintained by the Company resulted in rent expense for the years ended December 31, 2008 and 2007 of $75,467 and $79,941, respectively.

The Company has approximate future obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Public and Investor Relations	Total
2009	$3,300,000	$92,000	$53,000	3,445,000
2010	2,900,000	95,000	-	2,995,000
2011	200,000	96,000	-	296,000
2012	200,000	105,000	-	305,000
2013	200,000	115,000	-	315,000
Total	$6,800,000	$503,000	$53,000	$7,356,000

On February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by the Company's Board of Directors whereby, directly or indirectly, a majority of the Company's capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 750,000 to employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

11. Subsequent Events

On April 1, 2009, the Company will occupy office space in Princeton, New Jersey. The Company entered into a sub-lease agreement thru March 31, 2012. The Company is required to provide; 4 months of rent as a security deposit, the rent for the first 18 months will be $7,437.50 per month, or $17.00 per square foot. This increases to $7,656.25 per month of rent, or $17.50 per square foot for the remaining 18 months.

On March 12, 2009, the Company entered into a two-year employment agreement with Dr. Hamilton. Pursuant to this employment agreement the Company agreed to pay Dr. Hamilton a base salary of $270,000 per year. After one year of

service Dr. Hamilton would be entitled to a minimum annual bonus of $70,000. The Company agreed to issue him options to purchase 1,000,000 shares of its common stock, with the options vesting over three years. All vested options shall be exercisable for a period of one year following termination, subject to extension in the discretion of the Stock Option Administrator. Upon a change in control due to merger or acquisition, all of Dr. Hamilton'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 the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Hamilton's immediate family. Upon termination without "Just Cause" as defined by this agreement, the Company would pay Dr. Hamilton six months severance subject to set off if termination occurs during first full year of employment, as well as any accrued bonuses and accrued vacation would become payable.

On March 6, 2009, the Company entered into a $400,000 common stock equity investment agreement priced at market with its clinical trials management partner, Numoda. One hundred thousand dollars of this investment will be completed in January 2010. The investment follows and enhances the collaboration between the Company and Numoda announced on June 30, 2008 and represents partial payment by the Company under the collaboration agreement.

On February 11, 2009, the Company entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico (the Territory). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment, a $1 million payment, will be made upon the enrollment of the first patient in the Company's confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD, which is expected to occur in the second half of 2009. Total milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $10 million. Sigma-Tau will pay the Company a 35% royalty on net sales in the Territory, as well as pay for commercialization expense, including launch activities.

In connection with the execution of the collaboration and supply agreement, the Company entered into a common stock purchase agreement with Sigma-Tau pursuant to which the Company sold 25 million shares of common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price is equal to one hundred fifty percent (150%) of the average trading price of the Company's common stock over the five trading days prior to February 11, 2009. As part of the transaction, the Company granted Sigma-Tau certain demand and piggy-back registration rights.

On January 20, 2009, the Company received $2,384,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreement, the Company sold 20,914,035 common shares together with five year warrants to purchase up to 20,914,035 shares of the Company's common stock at $0.14 per share, for an aggregate price of $2,384,200 representing a price of $0.114 per share. The expiration date of the warrants can be accelerated if the Company's common stock meets certain price thresholds and the Company would receive additional gross proceeds of approximately $2.9 million if they are all exercised.

12. Business Segments

The Company had two active segments for the year ended December 31, 2008 and December 31, 2007: BioDefense and BioTherapeutics. Summary data:

	December 31, 2008	December 31, 2007
Net Revenues		
BioDefense	$ 2,269,647	$ 1,258,017
BioTherapeutics	40,618	-
Total	$ 2,310,265	$ 1,258,017
Loss from Operations		
BioDefense	$ (132,272)	$ (109,698)
BioTherapeutics	(1,556,429)	(2,748,764)
Corporate	(1,767,123)	(3,468,621)
Total	$ (3,455,824)	$ (6,327,083)
Identifiable Assets		
BioDefense	$ 1,076,854	$ 896,383
BioTherapeutics	650,179	552,248
Corporate	1,635,702	2,335,248
Total	$ 3,362,735	$ 3,783,879
Amortization and Depreciation Expense		
BioDefense	$ 85,354	$ 90,185
BioTherapeutics	58,829	24,312
Corporate	5,000	5,068
Total	$ 149,183	$ 119,565
Interest Income		
Corporate	$ 37,073	$ 164,847
Total	$ 37,073	$ 164,847
Stock Option Compensation		
BioDefense	$ 92,822	$ 69,591
BioTherapeutic	89,346	161,077
Corporate	203,448	446,733
Total	$ 385,616	$ 677,401

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, Ph.D. Chief Executive Officer and President

Date: March 27, 2009

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 27, 2009.

Signature	Title	Date
/s/ Christopher J. Schaber Christopher J. Schaber, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	March 27, 2009
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Director, Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 27, 2009
/s/ James S. Kuo James S. Kuo, M.D., M.B.A.	Chairman of the Board	March 27, 2009
_____ Cyrille F. Buhrman	Director	
/s/ Gregg A. Lapointe Gregg A. Lapointe, C.P.A., M.B.A.	Director	March 27, 2009
/s/ James Clavijo James Clavijo, C.P.A., M.A.	Controller, Treasurer, and Corporate Secretary	March 27, 2009

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