DOR BIOPHARMA INC
Form 10KSB
March 09, 2007

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

FORM 10-KSB

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

For the Fiscal Year Ended **December 31, 2006**

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

Commission File No. 1-14778

DOR BIOPHARMA, INC.
(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)
1101 Brickell Avenue, Suite 701-S Miami, FL	**33131**
(Address of principal executive offices	(Zip Code)

(786) 425-3848
(Issuer's telephone number, including area code)

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

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

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

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

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

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

Issuer's revenues for its most recent fiscal year: **$2,313,020**

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $38,000,000, (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 American Stock Exchange on March 1, 2007.

At March 1, 2007, 88,701,291 shares of the registrant's common stock were outstanding.

Transitional Small Business Disclosure Format (check one): **Yes o No x**

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PART I

Item 1. Description of Business.

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

A. Overview

We are a research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. We have filed a new drug application ("NDA") for our lead product orBec® (oral beclomethasone dipropionate) with the U.S. Food and Drug Administration (the "FDA") for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"), and have received a Prescription Drug User Fee Act ("PDUFA") date for the FDA to complete its review of all materials regarding orBec® of July 21, 2007. In addition, the FDA's Oncologic Drugs Advisory Committee ("ODAC") will review the NDA for orBec® on May 10, 2007. We have also filed a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicines Evaluation Agency ("EMEA") for orBec®, which has also been validated for review.

We were incorporated in 1987. We maintain two active segments: BioTherapeutics and BioDefense. Our business strategy is to: (a) prepare for the potential marketing approval of orBec® by the FDA and the EMEA; (b) conduct prophylactic use clinical trials of orBec® for the prevention of GI GVHD; (c) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) reinitiate development of our other biotherapeutics products namely LPM™-Leuprolide, and Oraprine™; (e) explore acquisition strategies under which the Company may be acquired by another company with oncologic or GI products; (f) identify a sales and marketing partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (g) secure government funding for each of our biodefense programs 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; and (i) acquire or in-license new clinical-stage compounds for development.

On January 3, 2007, we received $3 million under a non-binding letter of intent with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other DOR pipeline compounds until March 1, 2007. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. They have both prescription and consumer products in metablolic, oncology, renal and supplements. Under the terms of the letter of intent, Sigma-Tau has purchased $1 million of our common stock at the market price of $0.246 per share, representing approximately four million shares. Sigma-Tau paid an additional $2 million, which was to be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. On February 21, 2007, Sigma-Tau relinquished its exclusive rights under the letter of intent with regard to acquisition discussions. However, all other terms of the letter of intent remain in effect, and Sigma-Tau and us are engaged in discussions for a European collaboration relating to orBec®. Also, because no agreement was reached by March 1, 2007, we are obligated to return $2 million to Sigma-Tau by April 30, 2007. If we do not pay Sigma Tau back in cash by May 31, 2007, interest will accrue at a rate of 6% compounded annually and Sigma Tau will have the option in its sole discretion of converting the accrued amount into common stock at a price per share equal to 80% of the market price at the time the

payment is made.

On January 17, 2007, we received an unsolicited proposal from Cell Therapeutics, Inc. ("CTIC") to acquire us. The proposal from CTIC is subject to, among other things, the completion of satisfactory due diligence regarding clinical, regulatory, manufacturing and proprietary positioning for orBec®. Under the original proposed terms, CTIC would issue our stockholders 29,000,000 shares of CTIC's common stock, representing 19.9% of CTIC outstanding shares of common stock. Our warrant and option holders would receive shares of CTIC common stock in an amount determined using the Black Scholes pricing model. CTIC has reserved the right to offer cash as consideration for the warrants instead of CTIC common stock. In addition, CTIC is also offering the potential for an additional $15 million payment (in stock or cash at our option) upon receipt of the approval of the NDA for orBec®. Because of our exclusivity with Sigma-Tau until March 1, 2007 we did not have any discussions with them regarding this proposal. Since Sigma-Tau released us from the exclusivity period we have retained RBC Capital Markets Corporation ("RBC") to provide certain investment banking and financial advisory services in connection with this transaction and other possible acquisition and licensing transactions.

BioTherapeutics Overview

Through our BioTherapeutics Division, we are in the process of developing oral therapeutic products to treat unmet medical needs. Our lead product, orBec®, has been evaluated in a randomized, multi-center, double-blinded, placebo-controlled pivotal Phase 3 clinical trial for the treatment of GI GVHD, a serious and life-threatening gastrointestinal inflammation associated with allogeneic bone marrow or stem cell transplant therapy. orBec® demonstrated a statistically significant reduction in mortality during the prospectively defined Day 200 post-transplant period and positive trends on it's primary endpoint. While orBec® did not achieve statistical significance in time to treatment failure through Day 50 (p-value 0.1177), the primary endpoint of its pivotal trial, it did achieve statistical significance in other key outcomes such as median time to treatment failure through Day 80 (p-value 0.0226), and most importantly, it demonstrated a statistically significant survival advantage in comparison to placebo at 200 days post-transplant (p-value 0.0139) and at one year post-randomized (p-value 0.04).

We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the PDUFA the FDA will complete its review of all materials regarding orBec® by July 21, 2007. Additionally, on May 10, 2007 an ODAC panel will review the NDA. We also filed an MAA with the EMEA on November 3, 2006, which was validated on November 28, 2006.

To build upon the positive results obtained during development of orBec® for the treatment of GI GVHD, we will pursue a follow-on development program targeting the prevention of acute GVHD. This program will be a Phase 2 single center trial that will be conducted at the Fred Hutchinson Cancer Research Center. This study will enroll approximately 138 patients and is designed to assess the safety and efficacy of orBec® in preventing acute GVHD after allogeneic hematopoietic stem cell transplantation. We anticipate initiating this Phase 2 clinical trial in the second quarter of 2007.

We expect to initiate in mid-2007 our next pipeline development program in the biotherapeutics area, which is our LPMÔ (Lipid Polymer Micelle) drug delivery system to enhance the intestinal absorption of water-soluble drugs/peptides, like leuprolide. This system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides that are not readily absorbed in the GI tract. Leuprolide is both a candidate drug for further development in several indications, such as prostate cancer and endometriosis as well as a prototype for development of other similar non-absorbable, but water soluble drugs. Preclinical animal pharmacokinetic ("PK") data indicate high relative bioavailability of leuprolide in the 20-40% range. The mechanism for absorption by LPM is to promote the passive uptake through the opening of paracellular channels in intestinal epithelial tissue. Based on the work in animals, we anticipate conducting a Phase 1 PK safety and tolerability study in humans in mid-2007.

BioDefense Overview

In collaboration with two United States academic research institutions, we are developing vaccines to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits induce antibodies that neutralize the toxins from which they are derived. Through exclusive licenses with two Universities, we have secured important intellectual property rights related to these vaccines. Both of these are considered bioterrorism threats by the U.S. Department of Homeland Security ("DHS"), National Institute of Allergic and Infectious Diseases ("NIAID"), Department of Defense ("DOD") and Centers for Disease Control and Prevention ("CDC"). We are developing our biodefense countermeasures for potential U.S. government procurement pursuant to the Project Bioshield Act of 2004, which provides incentives to industry to supply biodefense countermeasures to the Strategic National Stockpile.

On September 13, 2004, we were awarded a $6,433,316 grant from the NIAID for RiVax™, our genetically engineered vaccine against ricin toxin, one of the most lethal plant toxins known to man. Ricin toxin can inflict serious damage to lungs and cause death if inhaled. The grant supports the process development for manufacturing of RiVax™, our recombinant vaccine against ricin toxin. The grant is based on milestones and certain budget amounts are earned as we meet milestones in the development of RiVax™. On September 29, 2006, we announced that we had been awarded a grant of approximately $4,800,000 from the NIAID over a three-year period for the continued development of RiVax™. This continuing grant supports additional characterization of the vaccine and animal testing that is necessary for obtaining FDA licensure under conditions where human efficacy testing is not ethical or permitted.

On January 30, 2006, we announced results of a Phase 1 clinical trial of RiVax™. This study was completed by investigators at the University of Texas Southwestern Medical Center ("UT Southwestern") led by Dr. Ellen Vitetta, Director of the Cancer Immunobiology Center at UT Southwestern. Results from the trial demonstrated that RiVax™ is safe and immunogenic after immunization with three monthly injections of vaccine, with volunteers developing antibodies against ricin toxin. The functional activity of the antibodies was confirmed by transferring serum samples from the vaccinated volunteers into mice, which then survived exposure to ricin toxin. Results of the study were published in the *Proceedings of the National Academy of Sciences*. Under the sponsorship of the NIH grant, we have developed a scaleable process for the manufacture of the subunit immunogen component of RiVax™, begun long term stability testing, and have developed a second generation formulation of RiVax™ which will be tested in a Phase 2 trial.

Our vaccine against botulinum neurotoxin, BT-VACC™, is a mucosally administered vaccine that protects against exposure to botulinum neurotoxins. Botulinum neurotoxin is the most potent natural toxin and is on the NIAID Category A list of biothreats. Based on promising preclinical results that demonstrate induction of protective immune responses via oral or intranasal vaccination, we anticipate that BT-VACC™ can be developed as either a stand alone vaccine or administered as a booster to the current injected vaccines. We are developing BT-VACC™ to be administered by the mucosal route since such vaccines induce more complete protection than injected vaccines and are thought to confer better protection against aerosol or oral exposure to botulinum neurotoxin. Since mucosally administered formulations can be given without needles and trained personnel, we expect that that BT-VACC™ will be poised for rapid distribution and vaccination for military use or civilian vaccination in response to bioterrorism. Any vaccine for botulinum will have to be composed of multiple antigens representing several natural serotypes. At this point, we have demonstrated that combinations of three serotypes can induce protective immune response in animals. The three serotypes are A, B, and E, which represent the most common of the botulinum serotypes and the ones most likely to be used as bioweapons. Our plans are to focus on development of the oral vaccine concept using formulation technology that permits increased contact of the antigen with immune inductive sites in the GI tract, and alternatively develop the A-B-E trivalent vaccine as a nasal spray vaccine. In conjunction with DOW Pharma, we have demonstrated that it will be feasible to manufacture the required antigens in a bacterial host (P. fluorescens), and are anticipating developing purification processes for each antigen. BT-VACC™ is covered by issued and pending U.S. patents.

On September 29, 2006, we announced that we had been awarded a Small Business Innovation Research ("SBIR") grant of approximately $500,000 from the NIAID over a one year period for further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. This grant will support further work in identifying an effective formulations technology that permits the oral administration of the three vaccine subunits in a single combination vaccine.

B. BioTherapeutics Division

1. orBec®

Our lead therapeutic product orBec® is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the PDUFA the FDA will complete and review of all materials regarding orBec® by July 21, 2007. Additionally, on May 9, 2007, the ODAC will review the NDA. We also filed an MAA with the EMEA on November 3, 2006, which was validated for review on November 28, 2006. We assembled an experienced team of consultants and contractors who worked on all aspects of the NDA preparation, including data management, data analysis, biostatistics, and medical writing. Manufacturing of the requisite NDA stability batches of drug product have been completed with the process validation batches anticipated to begin in the second quarter of 2007.

Both filings are supported by data from two randomized, double-blinded, placebo controlled clinical trials. The first was a 129 patient pivotal Phase 3 multi-center clinical trial for orBec® conducted at 16 bone marrow/stem cell transplant centers in the U.S. and France. The second was a 60 patient Phase 2 supportive clinical trial conducted at the Fred Hutchinson Cancer Center.

Comprehensive Long-Term Mortality Results

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

200 Days Post Transplant Mortality Results

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

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

In the pivotal Phase 3 clinical trial, survival at the pre-specified endpoint of 200 days post-transplant showed a clinically meaningful and statistically significant result. According to the manuscript, "the risk of mortality during the 200-day post-transplant period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p=0.03, Wald chi-square test)." Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely time to treatment failure through Day 50 (p=0.1177), orBec® did achieve statistical significance in other key outcomes such as reduction in the risk of treatment failure through Day 80 (p=0.0226) and, most importantly, demonstrated a statistically significant long-term survival advantage compared with placebo. The most common proximate causes of death by transplant day-200 were relapse of the underlying malignancy and infection. Relapse of the 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-transplant in the supportive Phase 2 clinical trial showed consistent response rates with the pivotal Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significantly different. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplant day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

In the pivotal Phase 3 trial, orBec® achieved these mortality results despite the fact that there where 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 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-transplant.

Safety and Adverse Events

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

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of GI GVHD to be approximately 70 percent of the more than 12,000 bone marrow and stem cell transplants that occur each year in the U.S.

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

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

Under the terms of the letter of intent, Sigma-Tau has purchased $1 million of our common stock at the market price of $0.246 per share, representing approximately four million shares. Sigma-Tau paid an additional $2 million in cash, which was to be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because no agreement was reached by March 1, 2007, we are obligated to return $2 million to Sigma-Tau by April 30, 2007. If we do not pay Sigma-Tau back in cash by May 31, 2007, interest will accrue at a rate of 6% compounded annually and Sigma-Tau will have the option in its sole discretion of converting the accrued amount into common stock at a price per share equal to 80% of the market price at the time the payment is made. On February 21, 2007, Sigma-Tau relinquished its exclusive rights under the letter of intent with regard to acquisition discussions. However, all other terms of the letter of intent remain in effect, and Sigma-Tau and us are engaged in discussions for a European collaboration relating to orBec®.

Research and Development

Since 2000, we have incurred expenses of approximately $15,000,000 in the development of orBec®. Research and development costs for orBec® totaled $3,019,756 in 2006 and $2,209,770 in 2005, of which $124,958 are for costs reimbursed under the FDA orphan products grant. If orBec® is approved by the FDA in the third quarter of 2007, we expect orBec® to begin generating revenues by the fourth quarter of 2007. If the FDA rejects the NDA or does not approve orBec® in a timely manner (or in accordance with anticipated and established timelines), our financial condition, liquidity, and ability to raise additional equity financing could be impaired.

To build upon the positive results obtained during development of orBec® for the treatment of GI GVHD, we will pursue a follow-on development program targeting the prevention of acute GVHD. This program will be a Phase 2 single center trial that will be conducted at the Fred Hutchinson Cancer Research Center. This study will enroll approximately 138 patients and is designed to assess the safety and efficacy of orBec® in preventing acute GVHD after allogeneic hematopoietic stem cell transplantation. We anticipate initiating this Phase 2 clinical trial in the second quarter of 2007. If the data from this clinical trial demonstrates positive results, the potential market for orBec® would expand to potentially include all patients in the U.S. who undergo allogeneic hematopoietic stem cell transplantation and who are at risk for developing acute GVHD.

About Graft-versus-Host Disease

Graft-versus-Host Disease occurs in patients following an allogeneic bone marrow transplant in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes in the donor (graft) marrow. Patients with mild to moderate 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 to 70% of the approximate 12,000 annual allogeneic transplant patients in the United States will develop some form of acute GI GVHD.

GI GVHD is one of the most common causes for the failure of bone marrow transplant procedures. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat GI GVHD.

Currently approved systemic immunosuppressives utilized to control GI GVHD substantially inhibit the highly desirable graft-versus-leukemia ("GVL") effect of bone marrow transplants, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

About Allogeneic Bone Marrow/Stem Stem Cell Transplantation (HSCT)

Allogeneic hematopoietic stem cell transplantation ("HSCT") is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HSCT 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 HSCT is now partly attributed to the so-called GVL or graft-versus-tumor ("GVT") effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HSCT 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 ("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 HSCT 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 HSCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplants have 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 HSCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

2. Future Potential Indications of orBec®

Based on its pharmacological characteristics, orBec® may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent (6,096,731) claiming the use of oral BDP as a method for preventing the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation, as well as GVHD, as occurs following organ allograft transplantation. We plan on initiating a Phase 2 trial of orBec® in the prevention of acute GVHD sometime in the second quarter of 2007. In addition, we are exploring the possibility of testing orBec® for local inflammation associated with Ulcerative Colitis, Crohn's Disease, Lymphocytic Colitis, Irritable Bowel Syndrome and liver disease, among other indications.

3. Other Products in BioTherapeutics Pipeline

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

LPM™ - Leuprolide

Lipid Polymer Micelle (LPM™). We are developing the LPMÔ system for enhancing the intestinal absorption of water-soluble drugs/peptides that are not ordinarily absorbed or are degraded in the gastrointestinal tract. As the first example of a peptide drug that can be delivered orally, we are developing an oral formulation of the peptide drug Leuprolide, a hormone drug that is among the leading drugs used to treat prostate cancer and endometriosis. The oral dosage form utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

Leuprolide is a potent analogue agonist of the Luteinizing Hormone Releasing Hormone ("LHRH"), currently used to treat hormone responsive prostate cancer in men, endometriosis in women, and precocious puberty in children. The current injected LHRH analog formulations are depot formulations that are designed to be injected under the skin and release Leuprolide in a controlled fashion over 1 to 4 months (Lupron® marketed by TAP Pharmaceuticals and Zoladex® marketed by Astra Zeneca) and for periods up to 6 months (Eligard®, marketed in the U.S. by Sanofi). Leuprolide is used in treating prostate cancer to slow the growth of the cancer. In children with central precocious puberty, Leuprolide reduces the levels of estrogen and testosterone. Estrogens promote the growth of abnormal uterine tissue that exists outside the uterus and thus Leuprolide is used to reduce the production of estrogen and treat both fibroids and endometriosis.

Based on promising preclinical data and high bioavailability achieved in animals with oral administration of Leuprolide in the LPM™ system, we believe that LPM™-Leuprolide may have a competitive role in a segment of the current Leuprolide market and effectively compete with the depot formulations of Leuprolide. Specifically we believe that LPM™ -Leuprolide can be developed as a once-a-day oral formulation that can maintain blood levels of Leuprolide resulting in suppression of estrogen production in women suffering from endometriosis. We believe there is a need for a better formulation of a LHRH-like product, such as LPM™-Leuprolide that will increase compliance and efficacy, with fewer side effects.

Research and Development

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

Cost and Development analysis for LPM™ Leuprolide

	2007	2008	2009	2010	2011
Pilot stability	$50,000	$150,000	$-	$-	$-
Process Development Scale up Product characterization	100,000	150,000			
Acute toxicity studies	100,000	250,000			
Clinical supply manufacture		250,000			
Phase 1 Clinical studies	150,000	300,000			
Animal dosing studies (efficacy)		250,000			
Phase 2 clinical (dose ranging)			1,500,000	500,000	
Phase 3 (endometriosis)				2,500,000	1,000,000
Manufacture - Characterization				750,000	
TOTALS	$400,000	$1,350,000	$1,500,000	$3,250,000	$1,000,000

We have completed proof of concept studies in rats and dogs. We first plan to conduct a small Phase 1 bioavailability study to compare the absorption of a enteric-coated gelatin capsule of LPMÔ-Leuprolide with an injected formulation. We anticipate initiating this trial in mid-2007. We then plan to conduct Phase 2 trials in volunteers to establish the proper dosing regimen before moving to Phase 3 trials in women with endometriosis when resources permit. Being able to move forward towards product launch and generation of revenue along the above timeline is highly dependent upon the results from the prior phase and ongoing interactions with the FDA. The scheduling of product launch is also highly dependent on being able to recruit sufficient numbers of patients for Phase 2 evaluation. We will have to raise additional funds in order to conduct later phase clinical trials. This may require partnering of the product at various stages during development.

The costs that we have incurred to develop LPM™-Leuprolide since 2000 total $1,248,324. Research and development costs for LPM™-Leuprolide totaled $3,900 in 2005 and $5,679 in 2006. These costs are mainly legal costs in connection with maintenance of our patent positions. It is our intention to out-license this program to another pharmaceutical company. If we are unable to develop LPM™-Leuprolide on our own, it would not have a material adverse effect on us.

Oraprine™

Oraprine™ is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. Also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Epstein that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus

host disease. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient. Oraprine™ may provide a convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

Based on the outcomes of two Phase 1 clinical trials of Oraprine™, we are planning to reformulate AZA (Oraprine™) as a stable oral liquid suspension with the intent of demonstrating bioequivalence to the branded oral azathioprine tablets currently marketed in the United States (Imuran® and Azasan®). One Phase 1 bioequivalence trial was conducted with an early formulation and demonstrated bioequivalence to the marketed product.

Research and Development

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

Cost and timeline analysis of Oraprine™ development.

	2007	2008	2009	2010	2011
Continued reformulation	$75,000	$-	$-	$-	$-
Pilot stability	50,000				
Formal stability	75,000	225,000			
Bioequivalence (Clinical) Adults		250,000	500,000		
Bioequivalence (clinical) - pediatric			500,000		
Juvenile Rheumatoid arthritis (RA)			1,000,000	500,000	
Toxicology				400,000	
Manufacture-Quality control			750,000	750,000	500,000
TOTALS	$200,000	$475,000	$2,750,000	$1,650,000	$500,000

The cost estimates in the table above are based upon conducting continued research into the development of a stable liquid formulation, which are planned to be completed before the end of 2007, with concurrent initiation of stability assessments. A series of bioequivalence studies are to be completed in adults and children by 2009, with trials to establish safety and efficacy in pediatric juvenile rheumatoid arthritis patients completed by 2010. Marketing approval with indications for kidney transplant and adult rheumatoid arthritis are anticipated by 2011, with generation of revenue by 2012. Market approval for Oraprine™ for juvenile rheumatoid arthritis is anticipated by 2012. The assumption in the above scenario is that we will develop the drug on our own without partners and market the drug through our own sales force. The premise behind the development of the drug under the ANDA strategy is that the technical objective of achieving a stable liquid formulation can be achieved in the light of the known chemical instability of azathioprine. Thus, the major milestone in 2007 is the completion of stability data with demonstration of acceptable drug stability. It is possible that, based on achievement of any of the milestones, we will achieve revenue through outlicensing and partnering arrangements.

The costs that we have incurred to develop Oraprine™ since 2000 total $415,096. Research and development costs for Oraprine™ totaled $8,100 in 2005 and $6,996 in 2006. These costs are mainly legal costs in connection with maintenance of our patent positions. It is our intention to out-license this program to another pharmaceutical company. If we are unable to develop Oraprine™ on our own, it would not be material.

LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs

We have also conducted initial research studies to identify drug delivery systems that promote the oral (intestinal) absorption of water insoluble drugs. One of the main difficulties in delivering drugs by the oral route is the low solubility of many therapeutic compounds. We have developed two novel delivery systems that we think will be useful for oral delivery of water insoluble drugs. One of these systems is based on emulsions composed of polymers (LPE, or lipid polymer emulsions) and another is a composed of solid lipid particles (PLP, or polymer lipid particles). We have conducted initial studies in animals that demonstrate that the LPE system used with the anticancer drug paclitaxel, the active drug in Taxol, promotes oral absorption with significant bioavailability in rodents in relationship to formulations of the injected drug. We believe that this example demonstrates the promise of using these systems for not only paclitaxel for further development but also for oral delivery of other water insoluble drugs. We anticipate that the general level of expenditure for pre-clinical research needed to advance oral LP-paclitaxel to Phase 1 studies, including preclinical toxicology evaluations, will be approximately $0.8 million, and will take 1-1.5 years.

The LPE™ system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents. We have filed for patent applications on the use of perillyl alcohol as a solvent, surfactant and absorption enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs.

C. BioDefense Programs

In collaboration with two United States academic research institutions, we are developing vaccines to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products produced in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits induce antibodies that neutralize the toxins from which they are derived. Through exclusive licenses with these Universities, we have secured intellectual property rights for these vaccines.

1. Rivax™ - Ricin Toxin Vaccine

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

On September 29, 2006, we announced that we had been awarded a grant of approximately $4,800,000 from the NIAID over a three year period for the continued development of RiVax™. This is in addition to the $6,433,316 already awarded by the NIAID. This new grant will 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.

Ricin Toxin

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

Research and Development

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

Cost and Development analysis for RiVax™

	2007	2008	2009	2010	2011
cGMP stability	$85,000	$-	$-	$-	$-
Adjuvant characterization	210,000				
Animal model development	500,000				
Vaccine/protection Inhaled ricin	295,000	295,000	295,000		
Clinical supply (3000 doses)	150,000				
Release and potency testing		250,000			
Human/animal correlation	130,000	130,000			
Phase 1/2 (dose determination)	150,000	1,250,000			
Pivotal animal studies (primates)			1,500,000		
Additional manufacture			750,000		
Other				50,000	50,000
TOTALS	$1,520,000	$1,925,000	$2,545,000	$50,000	$50,000

The costs that we have incurred to develop RiVax™ since 2002 total $6,360,523. Research and development costs for RiVax™ totaled $2,422,196 in 2005 of which $1,942,076 was for costs reimbursed under the NIH grant, and $2,130,516

in the second quarter of 2006, of which $1,128,257 was for costs reimbursed under this grant.

2. BT-VACC™ - Botulinum Toxin Vaccine

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. Botulinum toxin is the product of the bacteria *Clostridium botulinum*. Botulinum toxin is one of the most poisonous natural substances known. 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.

We are developing a multivalent vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. Currently, the recombinant vaccines under development are given by intramuscular injections. 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-VACC™ 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. The alternate route provides a self administration option, which will bypass the requirement for needles and personnel to administer the vaccine. We have identified lead antigens against Serotypes A, B and E consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date suggests that a bivalent formulation of serotypes A and B is effective at low, mid and high doses as an intranasal vaccine and 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.

Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create an oral dosage form, which we anticipate will improve immunogenicity and potency. We have been collaborating with Thomas Jefferson University to conduct vaccine efficacy experiments under a sponsored research agreement. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™ a high yield expression system based on *Pseudomonas fluorescens.*.

On September 29, 2006, we announced that we had been awarded a Small Business Innovation Research (“SBIR”) grant of approximately $500,000 from the NIAID over a one year period for further work to combine antigens from different serotypes of botulinum toxin for a prototype multivalent vaccine. The grant funding will support further work in characterizing antigen formulations.

The government has classified botulinum toxin as a Category A biothreat and has allotted up to $1.7 Billion under the current project BioShield bill. We are aware that the Department of Defense (“DoD”) has infused $200 Million into advanced development of an injectable vaccine for botulinum toxin, which is still in early clinical phases of development.

Research and Development

We have conducted a series of studies in animals that have demonstrated that the key immunogenic antigen derived from botulinum toxin can be given to animals orally and elicit a protective immune response. This has been shown

with a single serotype of botulinum toxin and recently the observation has been expanded to a prototype mixture of three antigens given to animals by intranasal immunization. We have used our own capital to invest in the demonstration of product feasibility since the inception of this project in 2003, but now are using grant funding to advance further product development. We have received a Phase 1 $0.5 Million SBIR grant from the NIH for project funding during 2007, and anticipate being able to obtain additional SBIR funding of $1.0-3.0 Million for 2008.

Cost and Development analysis for BT-VACC™

	2007	2008	2009	2010	2011
Definition of enteric formulation	$130,000	$-	$-	$-	$-
Stability characterization	50,000				
Animal efficacy	150,000	250,000			
Process development 3 components		150,000	350,000		
Assay development		250,000			
Scale up and production			500,000		
Toxicology evaluation			300,000		
Release/potency			200,000		
Phase 1 Safety/immunogenicity -volunteers			150,000		
Phase 2 +manufacture				5,000,000	4,000,000
Pivotal animal				1,500,000	500,000
TOTALS	$330,000	$650,000	$1,500,000	$6,500,000	$4,500,000

The costs that we have incurred to develop BT-VACC™ from 2002 total $2,104,767. Research and development costs for BT-VACC™ totaled $979,247 in 2005 and $130,381 in the second quarter of 2006.

3. Strategy for development of BioDefense products

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

purchase countermeasures upon expiration, so there is a recurrent market to replenish the stockpile. Under a $5.6 Billon appropriation bill over 10 years, the BioShield Act of 2004 authorizes the government to procure new countermeasures. This bill also allows the NIH to use simplified and accelerated peer-review and contracting procedures for research and development and empowers the FDA to approve distribution of unapproved medical products on an emergency basis. Further, additional legislation, such as the recently enacted Biomedical Advanced Research and Development Authority (BARDA) bill, may help provide funding for products at an intermediate state of development.

D. Summary of Our Products in Development

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

BioTherapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of gastrointestinal Graft-versus-Host Disease	NDA and MAA filed and under review
LPM™ - Leuprolide	Endometriosis and Prostate Cancer	Phase 1
Oraprine™	Oral lesions resulting from Graft-versus-Host Disease	Phase 1/2
LPE™ and PLP™ Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

Biodefense Products

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

F. The Drug Approval Process

1. General

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

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

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

Clinical trials are normally done in three Phases, although the phases may overlap. Phase 1 trials are concerned primarily 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 multi-center clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship, discover less common side effects and adverse reactions, and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 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 an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes may be required to be submitted to the FDA or foreign regulatory authority.

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

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

2. Marketing Strategies

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec® and sale or merger of all of our assets. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We are actively seeking a partner for orBec® for territories outside North America. We are actively seeking a partner for the development of other potential indications of orBec® as well as for our Oraprine™, LPM™ - Leuprolide, LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs. We also are actively considering a strategy of a commercial launch of orBec® by ourselves in the U.S.

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

3. Competition

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

A. Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Avant Immunotherapeutics, Inc., Dynavax, Emergent Biosolution (formerly Bioport Corporation), VaxGen, Inc., Chimerix, Inc., GlaxoSmithKline through acquisition of ID Biomedical Corporation, Human Genome Sciences, Inc., CpG Immunotherapeutics, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmatheneand others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. VaxGen and Avecia Biotechnology, Inc. have both received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen has also received approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of Anthrax vaccine. This contract was recently withdrawn by the HHS because of the inability of Vaxgen to enter into Phase 2 clinical trials according to contract timelines. Several companies have received development grants from NIH for biodfense products. For example, CpG Immunotherapeutics, Inc. has received a $6 million Department of Defense grant to develop vaccine enhancement technology. ID Biomedical Corporation, has entered into an $8 million contract to develop a plague vaccine in conjunction with Dynport Vaccine Company, LLC, a prime contractor with the DoD. Dynport Vaccine Company currently has a $200 million contract to develop vaccines for the U.S. Military, including a multivalent botulinum toxin vaccine. Although we have received significant grant funding to date for product development, we have not yet been obtained contract awards for government procurement of products.

B. orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat GVHD by suppressing the immune system through various mechanisms. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat graft-vs.-host disease. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat graft-vs.-host disease. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant related therapeutics. We face potential competition from Osiris Therapeutics if their product Prochymal for the treatment of GI GVHD is successful in ongoing Phase 3 clinical trials and reaches market. 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 Remicade™ for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®**.** Entocort is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In Italy, Chiesi Pharmaceuticals markets an oral formulation of beclomethasone dipropionate, the active ingredient of orBec® for ulcerative colitis and may seek marketing approval for their product in countries other than Italy including the United States. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis called Colazal®.

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

6. Patents and Other Proprietary Rights

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

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

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

Orphan Drug Act of 1983. We are the exclusive licensee of an issued U.S. patent that covers the use of orBec® for the prevention of GI GVHD.

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

7. orBec® License Agreement

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

Enteron also executed an exclusive license to patent applications for "Use of Anti-Inflammatories to Treat Irritable Bowel Syndrome" from the University of Texas Medical Branch-Galveston. Under the license agreements, we will be obligated to make performance-based milestone payments, as well as royalty payments on any net sales of orBec®.

8. Ricin Vaccine Intellectual Property

In January 2003, we executed a worldwide exclusive option to license patent applications with the University of Texas Southwestern Medical Center ("UTSW") for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine for initial license fees of $200,000 of our common stock and $100,000 in cash. Subsequently, in October of 2004, we negotiated the remaining oral rights to the ricin vaccine for additional license fees of $150,000 in cash. Our license obligates us to pay $50,000 in annual license fees.

On March 1, 2005 we signed a sponsored research agreement with UTSW extending through March 31, 2007. The cost of this research is approximately $190,000. We have additional sponsored research agreements with UTSW funded by two NIH grants. The research will grant us certain rights to such intellectual property. On December 7, 2006 we announced that the United States Patent and Trademark Office ("USPTO") issued a Notice of Allowance of patent claims based on U.S. Patent Application #09/698,551 entitled "Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin." This patent includes methods of use and composition claims for RiVax™.

9. Botulinum Toxin Vaccine Intellectual Property

In 2003, we executed an exclusive license agreement with Thomas Jefferson University for issued U.S. Patent No. 6,051,239 and corresponding international patent applications broadly claiming the oral administration of nontoxic modified botulinum toxins as vaccines. The intellectual property also includes patent applications covering the inhaled and nasal routes of delivery of the vaccine. This license agreement required that we pay a license fee of $160,000, payable in $130,000 of restricted common stock and $30,000 in cash. We also entered into a one-year sponsored research agreement with the execution of the license agreement with Thomas Jefferson University, renewable on an annual basis, under which we are providing $300,000 in annual research support. In addition, we also executed a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine for a period of three years. Under this agreement, Dr. Simpson received options to purchase 100,000 shares of our common stock, vesting over two years. We are also required to pay a $10,000 non-refundable license royalty fee no later than January 1 of each calendar year. We entered into an additional sponsored research agreement for $37,500 thru August 31, 2007.

10. Employees

As of March 1, 2007, we had eight full-time employees, three of whom are Ph.D.s.

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

12. Research and Development Spending

We spent approximately $4,800,000 and $3,700,000 in 2006 and 2005, respectively on research and development.

Cautionary Note Regarding Forward-Looking Statements

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

Risk Factors

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

Risks Related to our industry

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

We are a company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2006, we had approximately $120,000 in cash available. On January 3, 2007, we completed the sale of 4,065,041 shares of our common stock to Sigma-Tau for a purchase price of $1 million. On February 9, 2007, we completed the sale of an aggregate of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for an aggregate purchase price of $5,490,000 In addition, during 2007, we had warrant exercises in the amount of $677,312. Consequently, as of March 1, 2007, we had $7,089,092 in cash of which $2,000,000 is payable to Sigma-Tau. Based on our budgetary projections of $5,500,000 over the next 12 months, the financings will allow us to continue and maintain operations into the first quarter of 2008. In addition, our existing NIH biodefense grant facilities provide us with significant overhead contributions to continue to operate our business. On September 29, 2006, we announced that we had received approximately $5,300,000 in grants for the development of our biodefense programs. We estimate that the overhead revenue contribution from our existing NIH biodefense grants will generate an additional $850,000 over the next four quarters.

All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through December 31, 2006, we had expended approximately $17,400,000 developing our current product candidates for preclinical research and development and clinical trials,

and we currently expect to spend at least $6.0 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our leading product candidate, or another one of our product candidates, we may require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

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

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

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

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

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

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may be unable to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed. The pivotal clinical trial of our product candidate orBec® began in 2001. In December of 2004, we announced top line results for our pivotal Phase 3 trial of orBec® in GI GVHD, in which orBec® demonstrated a statistically significant reduction in mortality during the prospectively defined Day 200 post-transplant period and positive trends on its primary endpoint. While orBec® did not achieve statistical significance in its primary endpoint of time to treatment failure at Day 50 (p-value 0.1177), orBec® did achieve a statistically significant reduction in mortality compared to placebo. Additional clinical trials may be necessary prior to approval by the FDA of a marketing application.

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

There may be unforeseen challenges in developing biodefense products.

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

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

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products.

Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

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

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

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

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

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

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

Our products, if approved, may not be commercially viable due to health care changes and third party reimbursement limitations.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from, the University of Texas Southwestern Medical Center, The University of Texas Medical Branch at Galveston, Thomas Jefferson University, Southern Research Institute, the University of Alabama Research Foundation, and George B. McDonald M.D. for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

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

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

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

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $5 million, which

may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

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

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

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

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

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

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

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

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

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

We have only eight 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, Chief Executive Officer, was hired in August 2006; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was on the Board for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. We will not be successful if this management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

Our stock price has fluctuated between January 1, 2003 through December 31, 2006, the per share price of our common stock ranged between a high of $1.71 per share to a low of $0.20 per share. As of March 1, 2007, our common stock traded at $0.55. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock trades on the over the counter bulletin board and our stock is not listed on the American Stock Exchange

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

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

If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Our common stock is subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than $5.00 per share, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, our common stock could be priced at a lower price and our stockholders could find it more difficult to sell their shares.

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 approximately 34,400,000 shares of our common stock at a current weighted average exercise price of approximately $0.69;

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

    - options to purchase approximately 11,900,000 shares of our common stock of a current weighted average exercise price of approximately $0.50.

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

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 became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give 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.

Item 2. Description of Property

We currently lease approximately 2,500 square feet of office space at 1101 Brickell Avenue, Suite 701-S, Miami, Florida 33131. The office space currently serves as our corporate headquarters located in Miami, Florida. We pay rent of approximately $5,844 per month, or $28 per square foot, on a ten-month lease, which was entered into on August 7, 2006 and expires on June 23, 2007. We believe that our current leased facilities are sufficient to meet our current needs. We do anticipate that we will seek a new facility in the second quarter of 2007.

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.

On October 26, 2006, we received a summons in a civil case (Case No. 06-22629-CIV-COOKE/Brown, United States District Court for the Southern District of Florida]) from Michael T. Sember, our former President and Chief Executive Officer. The complaint claims that we breached the employment agreement entered into with Mr. Sember on December 7, 2004, specifically in the payment of his bonus. We have paid his severance and accrued vacation according to the terms of his employment agreement. Under the terms of this agreement, we have paid Mr. Sember $150,000 in severance and $28,383 for accrued vacation time, over a six month period beginning in August 2006. We deny the merit of the claim, as it is contrary to what is specifically stated in the agreement. On August 25, 2006, Mr. Sember was dismissed without “Just Cause” (as such term is defined in the agreement). Our position is that, upon termination of Mr. Sember without Just Cause, he was to be paid six months severance, any unpaid bonuses, and any vacation time accrued but not taken. The complaint contends that a minimum annual bonus of $100,000 was due. In addition, Mr. Sember is also seeking costs and attorney’s fees incurred for this action. We deny that we owe Mr. Sember any bonus and will vigorously defend against Mr. Sember’s claim that he is entitled to a bonus of $100,000.

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

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

The Annual Meeting of our shareholders was held on January 24, 2007. Of the 68,778,401 shares of the our common stock outstanding on the record date of November 3, 2006, a total of 51,606,868 shares of common stock were present in person or by proxy.

The following directors were re-elected at the meeting:

	For	Withheld Authority
Steve H. Kanzer, JD, CPA	50,564,104	1,042,764
James S. Kuo, MD	50,956,695	650,173
Evan Myrianthopoulos	50,940,829	666,039
Christopher J. Schaber, PhD	50,957,613	649,255

The shareholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 to 250,000,000. Of the votes cast on this matter, 50,472,015 shares voted for the approval of the amendment, 1,124,934 shares voted against the matter, 9,919 shares abstained from voting on the matter and there were 0 shares representing broker non-votes on the matter.

The shareholders ratified the appointment of Sweeney, Gates & Co., as our independent auditors for the year ending December 31, 2006. Of the votes cast on this matter, 51,177,660 shares voted for the approval of the amendment, 197,135 shares voted against the matter, 232,073 shares abstained from voting on the matter and there were 0 shares representing broker non-votes on the matter.

PART II

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

Our common stock is traded on the Over The Counter Bulletin Board ("OTCBB") under the symbol "DORB." The table below sets forth the high and low sales prices, as provided by the American Stock Exchange and as reported on the Website of the OTCBB, for the period from January 1, 2005 through December 31, 2006. Until April 18, 2006, our common stock was listed on the American Stock Exchange. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.
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Period	Price Range	
	High	**Low**
Fiscal Year Ended December 31, 2005:		
First Quarter	$0.67	$0.35
Second Quarter	$0.42	$0.29
Third Quarter	$0.45	$0.32
Fourth Quarter	$0.36	$0.22
Fiscal Year Ended December 31, 2006:		
First Quarter	$0.69	$0.26
Second Quarter	$0.40	$0.23
Third Quarter	$0.33	$0.20
Fourth Quarter	$0.30	$0.21

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of March 1, 2007, the last reported price of our common stock was $0.55 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 1,089 registered holders of record.

Dividend Policy

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

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

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

Business Overview and Strategy

We are a research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. We have filed a new drug application ("NDA") for our lead product orBec® (oral beclomethasone dipropionate) with the U.S. Food and Drug Administration (the "FDA") for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"), and have received a Prescription Drug User Fee Act ("PDUFA") date for the FDA to complete its review of all materials regarding orBec® of July 21, 2007. In addition, the FDA's Oncologic Drugs Advisory Committee ("ODAC") will review the NDA for orBec® on May 10, 2007. We also have filed a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicines Evaluation Agency ("EMEA") for orBec®, which has been filed and validated for review.

Our business strategy is to: (a) prepare for the potential marketing approval of orBec® by the FDA and the EMEA; (b) conduct prophylactic use clinical trials of orBec® for the prevention of GI GVHD; (c) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) reinitiate development of our other biotherapeutics products namely LPM™-Leuprolide, and Oraprine™; (e) explore acquisition strategies under which the Company may be acquired by another company with oncologic or GI symmetry; (f) identify a sales and marketing partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (g) secure government funding for each of our biodefense programs 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; and (i) acquire or in-license new clinical-stage compounds for development. We were incorporated in 1987. We maintain two active segments: BioTherapeutics and BioDefense.

On January 17, 2007, we received an unsolicited proposal from Cell Therapeutics, Inc. ("CTIC") to acquire us. The proposal from CTIC is subject to, among other things, the completion of satisfactory due diligence regarding clinical, regulatory, manufacturing and proprietary positioning for orBec®. Under the original proposed terms, CTIC would issue our stockholders 29,000,000 shares of CTIC's common stock, representing 19.9% of CTIC outstanding shares of common stock. Our warrant and option holders would receive shares of CTIC common stock in an amount determined using the Black Scholes pricing model. CTIC has reserved the right to offer cash as consideration for the warrants instead of CTIC common stock. In addition, CTIC is also offering the potential for an additional $15 million payment (in stock or cash at our option) upon receipt of the approval of the NDA for orBec®. We have retained RBC Capital Markets Corporation ("RBC") to provide certain investment banking and financial advisory services in connection with this transaction and other possible acquisition and licensing transactions.

On January 3, 2007 we received $3 million under a non-binding letter of intent with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other DOR private offering compounds until March

1, 2007. 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 metablolic, oncology, renal and supplements. Under the terms of the letter of intent, Sigma-Tau purchased $1 million of our common stock at the market price of $0.246 per share, representing approximately four million shares. Sigma-Tau paid an additional $2 million, which was to be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because no agreement was reached by March 1, 2007, we are obligated to return $2 million to Sigma-Tau by April 30, 2007. If we do not pay Sigma-Tau back in cash by May 31, 2007, interest will accrue at a rate of 6% compounded annually and Sigma-Tau will have the option in its sole discretion of converting the accrued amount into common stock at a price per share equal to 80% of the market price at the time the payment is made. We are currently under active discussions regarding a potential European partnership.

orBec®

Our lead therapeutic product orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the PDUFA the FDA will complete its review of all materials related to orBec® by July 21, 2007. Additionally, on May 10, 2007 the FDA's Oncology Drug Advisory Committee will review the NDA. We also filed an MAA with the EMEA on November 3, 2006, which was validated for review on November 28, 2006. We have assembled an experienced team of consultants and contractors who worked on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GI GVHD to be approximately 70 percent of the approximately 12,000 bone marrow and stem cell transplants that occur each year in the U.S.

We have had strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of orBec®. We may seek a marketing partner in the U.S. and abroad in anticipation of commercialization of orBec®. We also intend to seek a partner for the other potential indications of orBec®. We are also actively considering an alternative strategy of a commercial launch of orBec® by ourselves in the U.S.

RiVax™

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

BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. Botulinum toxin is the product of the bacteria *Clostridium*

botulinum. Botulinum toxin is one of the most poisonous natural substances known. 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.. 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-VACC™ 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 to date suggests that a bivalent formulation of serotypes A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in 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.

LPM™ - Leuprolide

Lipid Polymer Micelle (LPM™)-Leuprolide is an oral dosage formulation of the peptide drug leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, which utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

Oraprine™

Oraprine™ is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We acquired the azathioprine drug (Oraprine™) as a result of the merger of Endorex and CTD in November 2001. Also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Epstein that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient. Oraprine™ may provide a convenient dosage form for patients who have difficulty swallowing pills or tablets, such as children.

LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs

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

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate these estimates and judgments.

Intangible Assets

Currently, the most significant estimate or judgment that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". Based on this consideration, we capitalized all outside legal and filing costs incurred in the procurement and defense of patents.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

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

We capitalize intangible assets that have alternative future uses; this is common in the pharmaceutical development industry. Of the intangible asset balance, $1,025,000 is for up-front license costs. We purchased a license from the University of Texas Southwestern Medical Center, for the license to the RiVax™ vaccine for $425,000. We also purchased a license from a “pharmaceutical company” namely Southern Research Institute/Brookwood Pharmaceuticals, for a license of microsphere technology for $600,000. We capitalize license costs because they have alternative future use as referred to in paragraph 11 c. of SFAS No.2. We believe that both of these intangible assets purchased have alternative future uses.

We capitalize legal costs associated with the protection and maintenance of our patents. We have drug and vaccine products in an often lengthy basic and clinical research process, we believe that patent rights form 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.

During 2006, we capitalized $206,004 in patent related costs. This amount is represented in the cash flow statement, in the section for investing activities presented in the 2006 10-KSB financial statements. On the balance sheet this amount is presented on the line intangible assets, net in the amount of $1,073,239.

Research and Development Costs

Research and Development costs are charged to expense when incurred. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies

and materials, salaries and employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense (IPR&D) represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Revenue Recognition

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

Material Changes in Results of Operations

We are a research and development company. The 2006 revenues and associated expenses were from NIH Grants received in September 2004 and September 2006, and for an FDA grant which we received in September 2005. The NIH grants were associated with our ricin and botulinum vaccines. The original amount of the first NIH grant was $5,173,298. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a new renegotiated F&A (facilities and administrative) rate with the NIH. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005. This new rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded. The new rate was a provisional rate and the final rate has not yet been finalized but the expectations are that the rate will be lower. In anticipation of this, we estimated that a charge in the amount of approximately $390,000 was necessary. The second NIH grant was received for ricin in September 2006 for $5,203,405. The NIH SBIR grant for botulinum was received in September 2006 for $465,191. We were awarded a one year FDA grant on September 23, 2005 for the "Oral BDP for the Treatment of GI GVHD" in the amount of $318,750.

For the year ended December 31, 2006 we had grant revenues of $2,313,020 as compared to $3,075,736 in the 12 months ended December 31, 2005, a decrease of $762,716, or 25%. We also incurred expenses related to revenues in 2006 and 2005 of $1,965,074 and $2,067,034, respectively, a decrease of $101,960, or 5%. These costs relate to payments made to subcontractors and universities in connection with the grants. The decrease in revenues and related expenses from 2005 are related to the accelerated progress made on the grants in late 2005 and early 2006. Additionally, the decrease is related to a charge in the amount of $390,000 for the expectations of a lower overhead rate and that the 2005 revenues included $285,891 that was attributed to the NIH reimbursement for overhead expenses for 2004 but which was received in the second quarter of 2005.

For the year ended December 31, 2006 the gross profit was $347,946 as compared to $1,008,702, in the 12 months ended December 31, 2005, a decrease of $660,756, or 66%. This was due to the decreased grant revenues in the year ended 2006 that were eligible for the F&A rate and the expected decrease in the final F&A rate.

Research and development spending increased by $121,702, or 3%, to $3,638,493, for the year ended December 31, 2006 as compared to $3,516,791 for the corresponding period ended December 31, 2005. Expenses remained consistent as we continue the regulatory and filing costs associated with the preparation and completion of the NDA filing for orBec®.

In-process research and development expenditures were $981,819 as compared to zero for year ended December 31, 2006 an increase of 100% for the same period ended December 31, 2005. This was due to the purchase of all of the remaining outstanding common stock of its majority owned subsidiary Enteron that the Company did not already own.

Impairment expense for intangibles was $816,300 as compared to $164,246 for the year ended December 31, 2006 an increase of 397% for the same period ended December 31, 2005. This was due to the impairment of the Southern Research Institute/Brookwood Pharmaceuticals, license of microsphere technology.

General and administrative expenses for the 12 months ended December 31, 2006 were $3,110,882 as compared to $2,162,616 for the 12 months ended December 31, 2005, an increase of $948,266, or 44%. The increase was due to stock option expense of $557,182 for stock options vested and issued in the year ended December 31, 2006 under the new accounting treatment under SFAS No. 123R. Additionally, we had non-recurring acquisition costs of approximately $116,000 associated with the unconsummated acquisition of Gastrotech Pharma A/S. This increase was also in part attributed to a recovery of $284,855 in 2005 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that exceeded the number of allowed stock

options under the plan which expenses did not occur in 2006.

Interest income for the 12 months ended December 31, 2006 was $41,510 as compared to $78,242 for the 12 months ended December 31, 2005, a decrease of $36,733 or 47%. This decrease was primarily due to a lower cash balance in 2006 as compared to 2005.

Interest expense for the 12 months ended December 31, 2006 was $5,308 as compared to $36,549 credit for the 12 months ended December 31, 2005, a decrease of $41,857 or 115%. This decrease was primarily due to recovery of interest because of an agreement reached with a pharmaceutical company for settlement of a note payable in 2005. This agreement required a payment of $41,865 in lieu of the $83,729 of interest we had accrued.

For the 12 months ended December 31, 2006, we had a net loss of $8,163,346 as compared to a $4,720,260 net loss for the 12 months ended December 31, 2005, a decrease of $3,443,086, or 73%. This increase is primarily attributed to the greater regulatory and filing costs associated with the preparation of the NDA filing for orBec®, the in-process research and development expense of $981,819 for acquiring all of the outstanding common stock of Enteron the Company did not already own, adjustments to revenue as described in the preceding paragraphs of $390,000 and $285,891, and an impairment expense for intangibles of $816,300.

Financial Condition

Cash and Working Capital

As of December 31, 2006, we had cash of $119,636 as compared to $821,702 as of December 31, 2005 and negative working capital of $2,211,387 as compared to negative working capital of $319,675 as of December 31, 2005. For the 12 months ended December 31, 2006, our cash used in operating activities was approximately $4,100,000, versus approximately $4,700,000 in 2005.

As of March 1, 2007 we had cash of $7,089,092 of which $2,000,000 is currently obligated to Sigma-Tau.

Expenditures

We expect our expenditures for 2006, under existing product development agreements and license agreements pursuant to letters of intent and option agreements to approximate $3,600,000. We anticipate grant revenues in the next twelve months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $3,600,000 with $800,000 contributing towards our overhead expenses.

The table below details our costs for 2006 and 2005 by project.

	2006	**2005**
Projects-Research & Development Expenses		
orBec®	$ 3,060,778	$ 2,045,424
RiVax™	274,635	480,120
BT-VACC™	290,405	979,247
Oraprine™	6,996	8,100
LPM™-Leuprolide	5,679	3,900
Research & Development Expense	$ 3,638,493	$ 3,516,791
Projects-Reimbursed under Grant		
orBec®	$ -	$ 124,958
RiVax™	1,961,074	1,942,076
BT-VACC™	4,000	-
Oraprine™	-	-
LPM™-Leuprolide	-	-
Reimbursed under Grant	$ 1,965,074	$ 2,067,034
TOTAL	$ 5,603,567	$ 5,583,825

Debt

We had no notes payable at December 31, 2006 or at December 31, 2005. During 2005, we paid a note payable of $115,948, which represented the remaining balance to a pharmaceutical company in connection with our joint ventures.

Leases

The following summarizes our contractual obligations at December 31, 2006, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	Year 2007	Year 2008	Year 2009
Non-cancelable obligation (1)	$ 33,706	$ -	-
TOTALS	**$ 33,703**	**$ -**	**$ -**

(1) On August 7, 2006 we signed a 10 month lease at a new location.

Equity Transactions

Subsequent to year-end, on February 9, 2007, we completed the sale of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for a purchase price of $5,490,000. We are filing a registration statement with the Securities and Exchange Commission covering the shares of common stock issued.

Subsequent to year-end, 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 has 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 were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. Because no agreement was reached by March 1, 2007, we are obligated to return the $2 million to Sigma-Tau by April 30, 2007. If we do not repay Sigma-Tau by May 31, 2007, interest will accrue at a rate of 6% compounded annually and Sigma Tau will have the option, at its sole discretion, of converting the accrued amount into common stock at a price per share equal to 80% of the market price at the time payment is made.

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

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion"). The Fusion facility allowed them to purchase on each trading day $20,000 of our common stock up to an aggregate of $6,000,000 million over approximately a 15-month period. As part of this agreement we issued Fusion 512,500 shares of common stock as a commitment fee. During 2006 Fusion purchased 329,540 common shares for $ 124,968. At this point in time we have no plans to utilize the Fusion facility.

In February 2005, we increased our cash position by the issuance and sale of 8,396,100 shares of our common stock at $0.45 per share in a private placement to institutional investors. These investors also received warrants to purchase 6,297,075 shares of our common stock at an exercise price of $0.505 per share. The proceeds after related expenses and closing costs were approximately $3.5 million. We do not believe these warrants require application of

SFAS No. 133. We determined this based on two interpretations of SFAS No. 133. First, the warrants have no initial allocable investment (paragraph 8 of SFAS No. 133). All three classes of warrants in question were issued in connection with private placements whose participants purchased units that included upfront shares as well as a certain percentage of out-of-the-money warrants deemed to have some future benefit. Second, all three classes of warrants are "regular-way" security trades as described in paragraph 10 of SFAS No. 133. Once exercised for cash, the warrant holders are issued common stock shares within three business days as required by public exchanges.

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

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

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

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

Based on our current rate of cash outflows, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into first quarter of 2008. It is possible that within the upcoming twelve months we will seek additional capital in the private and/or public equity markets to expand our operations, to respond to competitive pressures, to develop new products and services and to support new strategic partnerships. We may obtain capital pursuant to one or more corporate partnerships relating to orBec®. If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms or at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

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

Item 7. Financial Statements.

See Item 13(1) of this Annual Report.

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

None.

Item 8A. Controls and Procedures

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

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

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

Item 8B. Other Information

None.

PART III

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

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

Name	Age	Position
James S. Kuo, M.D., M.B.A.	42	Chairman of the Board
Steve H. Kanzer, C.P.A., J.D.	43	Vice Chairman
Christopher J. Schaber, Ph.D.	40	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	42	Chief Financial Officer, and Director
James Clavijo, C.P.A., M.A.	41	Controller, Treasurer, and Corporate Secretary

James S. Kuo, M.D., M.B.A., has been a director since 2004 and currently serves as the non-executive Chairman of the Board. Since 2006, he has served as President 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. From 2001 to 2002, he served as President and Chief Executive Officer of Microbiotix, Inc., a private, anti-infectives drug development 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 has held senior licensing and business development positions at Pfizer, Inc. and Myriad Genetics, Inc. Dr. Kuo has also been the Managing Director of Venture Analysis at HealthCare Ventures, LLC and Vice President at Paramount Capital Investments, LLC. Dr. Kuo is further a founder of ArgiNOx Pharmaceuticals, Inc., and Monarch Labs, LLC. Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

Steve H. Kanzer, C.P.A., J.D., has been a director since 1996 and currently serves as the non-executive Vice Chairman of the Board. Mr. Kanzer served as our Interim President from June 30, 2002 through January 4, 2003. Since February 2001, Mr. Kanzer has served as Chairman and Chief Executive Officer, and from February 2001 until May 2006 also as President, of Pipex Therapeutics, Inc. (“Pipex”), a specialty pharmaceutical company in Ann Arbor, Michigan developing oral late stage drug candidates for CNS and fibrotic diseases. He also serves as President and/or a member of the board of directors of several of Pipex’s subsidiaries, including CD4 Biosciences, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. and Solovax, Inc. Since December 2000, he has served as Chairman of Accredited Ventures Inc. and Accredited Equities Inc., respectively, a venture capital firm and NASD member investment bank specializing in the biotechnology industry. From January 2001 until October 2003, Mr. Kanzer also served as President of Developmental Therapeutics, Inc. until its acquisition by Titan Pharmaceuticals, Inc. in October

2003. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer was a co-founder of Paramount Capital, Inc. in 1992 and served as Senior Managing Director - Head of Venture Capital of Paramount Capital until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies, including our company as well as a private biopharmaceutical company, Corporate Technology Development, Inc. ("CTD"). Mr. Kanzer was full-time Chief Executive Officer of CTD from March 1998 until December 2000 and part-time Chief Executive Officer from December 2000 until our company completed its acquisition of CTD in November 2001. From 1995 until June 1999, Mr. Kanzer was a founder and Chairman of Discovery Laboratories, Inc., a public biotechnology company. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York. Mr. Kanzer received his J.D. from New York University School of Law and a B.B.A. in accounting from Baruch College where he was a Baruch Scholar.

Christopher J. Schaber, Ph.D., has been a director since August 2006 and is the President and Chief Executive Officer. Prior to joining, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc. where he was responsible for their operations including all drug development and commercial launch activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, a M.S. in Pharmaceutics from Temple University School of Pharmacy and a Ph.D. in Phamaceutical Sciences from The Union Graduate School.

Evan Myrianthopoulos, has been a director since 2002 and is currently the Chief Financial Officer after joining 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 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 negotiated and managed Discovery's mergers with Ansan Pharmaceuticals and Acute Therapeutics, Inc. Prior to co-founding Discovery, 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, Mr. Myrianthopoulos was a managing partner of S + M Capital Management, a hedge fund which specialized in syndicated stock offerings and also engaging in arbitrage of municipal and mortgage bonds. Prior to that, Mr. Myrianthopoulos held senior positions in the treasury department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr. Myrianthopoulos holds a B.S. in Economics and Psychology from Emory University.

James 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 DOR, Mr. Clavijo, held the position of Chief Financial Officer for Cigarette Racing Team (Miami, FL), from July 2003 to October 2004. During his time with Cigarette he was instrumental in developing a cost accounting manufacturing tracking system and managed the administration and development of an IRB Bond related to a 10 acre, 100,000 square foot facility purchase. Prior to joining Cigarette Racing Team, Mr. Clavijo held the position of Chief Financial Officer for Gallery Industries, from November 2001 to July 2003, a retail and manufacturing garment company. Prior to joining, Gallery, he served as Corporate Controller, for A Novo Broadband, from December 2000 to November 2001, a repair and manufacturing telecommunications company where he managed several mergers and acquisitions and corporate restructuring. Prior to joining A Novo Broadband, he served as Chief Financial Officer of AW Industries, from August 1997 to December 2000, a computer parts manufacturer. He also, held the position of Finance Manager for Wackenhut Corporation in the U.S. Governmental Services Division. In addition, he served in

the U.S. Army from 1983 to 1996 in both a reserve and active duty capacity for personnel and medical units. Mr. Clavijo holds a Master in Accounting degree from Florida International University, a Bachelor in Accounting degree from the University of Nebraska, and a Bachelor in Chemistry degree from the University of Florida. Mr. Clavijo is a licensed Certified Public Accountant in the state of Florida.

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, 2006, our officers, directors and significant stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act, except a Form 4 for Evan Myrianthopoulos (one filing) and a Form 4 for James Clavijo (one filing).

Code of Ethics

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

Audit Committee Financial Expert

We have an audit committee comprised of Dr. Kuo and Mr. Kanzer. The board of directors has determined that both Dr. Kuo and Mr. Kanzer 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 all of the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee.

Item 10. Executive Compensation.

Summary Compensation

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

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber (1)	CEO & President	2006	$104,700	$33,333	$185,403	$16,895	$340,331
Michael Sember (2)	CEO & President	2006	$192,500	-	$82,060	$229,827	$504,387
Evan Myrianthopoulos (3)	CFO	2006	$195,724	$55,000	$103,064	$49,257	$398,045
James Clavijo (4)	Controller, Treasurer & Secretary	2006	$144,999	$40,000	$42,836	-	$222,835

(1) Dr. Schaber began his employment with us on August 29, 2006. Dr. Schaber deferred payment of his 2006 prorated annual bonus of $33,333. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation includes costs for transportation, travel and lodging.

(2) Mr. Sember's employment was terminated without "just cause" on August 25, 2006. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation includes $150,000 in accrued severance payments and $28,383 for accrued vacation time, as well as costs for transportation, travel and lodging.

(3) Mr. Myrianthopoulos joined in November 2004 as President and Acting Chief Executive Officer and then in December 2004 he accepted the position of Chief Financial Officer. Mr. Myrianthopoulos deferred payment of his 2006 annual bonus of $55,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation includes costs for transportation, travel and lodging.

(4) Mr. Clavijo joined in October 2004. Mr. Clavijo deferred payment of his 2006 annual bonus of $40,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R.

Potential Issuance of Shares

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

Employment and Severance Agreements

During August 2006, we entered into a three year employment agreement with Christopher J. Schaber, Ph. D. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. We agreed to issue him options to purchase 2,500,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber six 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.

During December 2004, we entered into a three year employment agreement with Michael T. Sember, Pursuant to this employment agreement we agreed to pay Mr. Sember a base salary of $300,000 per year. After one year of service Mr. Sember would be entitled to a minimum annual bonus of $100,000. We agreed to issue him options to purchase 2,000,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. This option grant was subject to shareholder approval. Upon termination without "Just Cause" as defined by this agreement, we would pay Mr. Sember six months severance, as well as any unpaid bonuses and accrued vacation. No unvested options shall vest beyond the termination date. On August 25, 2006 we terminated the employment agreement with Mr. Sember without 'Just Cause." Mr. Sember remained with us as a director until he resigned on September 25, 2006. We have paid his severance and accrued vacation according to the terms of his employment agreement. His employment agreement required us to pay him $150,000 in severance and $28,383 in accrued vacation. At the time of Mr. Sember's termination he had vested options to purchase 1,340,000 of our common stock. Mr. Sember did not have any unpaid bonuses at the time of his termination.

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

During May 2006, we increased Evan Myrianthopoulos' base salary to $200,000. We also agreed to issue him 400,000 options of our common stock, with 100,000 options immediately vesting and the remainder vesting over three years.

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

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers during the fiscal year ended December 31, 2006. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (S)	Option Expiration Date
	Exercisable	Unexercisable			
Christopher J. Schaber(1)	972,223	1,527,777	1,527,777	$0.27	8/28/2016
Michael T. Sember(2)	1,340,000	-	-	$0.46	8/24/2007
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
	333,336	166,664	166,664	$0.49	12/13/2014
	150,000	250,000	250,000	$0.35	5/10/2016
James Clavijo	66,666	33,334	33,334	$0.45	10/22/2014
	116,664	33,336	33,336	$0.45	2/22/2015
	87,500	112,500	112,500	$0.33	5/10/2016

(1) Dr. Schaber began his employment with us on August 29, 2006.
(2) Mr. Sember’s employment was terminated without “Just Cause” on August 25, 2006.

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2006.

Director Compensation

Name	Fees Earned of Paid in Cash ($) (1)	Option Awards ($) (2)	Total ($)
Steve H. Kanzer	$25,000	$11,270	$36,270
James S. Kuo	$25,000	$11,270	$36,270

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

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

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

The table below provides information regarding the beneficial ownership of the Common Stock as of March 1, 2007 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. Except as otherwise indicated, each stockholder's percentage ownership of our common stock in the following table is based on 88,701,291 as of March 1, 2007 shares of common stock outstanding.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
SouthPointe Master Fund, LP (1)	8,510,638	9.6%
Cyrill F. Buhrman(2)	4,900,020	5.2%
Platinum Partners Long Term Growth III (3)	4,604,306	