DOR BIOPHARMA INC
Form 424B3
April 11, 2008

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Registration No. 333-149239

PROSPECTUS

DOR BioPharma, Inc.

26,563,613 Shares of Common Stock

This prospectus relates to the sale of up to 26,563,613 shares of our common stock by the selling stockholders named in this prospectus in the section “Selling Stockholders,” whom we refer to in this document as the “selling stockholders.” The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of any of the shares covered by this prospectus. References in this prospectus to the “Company,” “we,” “our,” and “us” refer to DOR BioPharma Inc.

Our common stock is quoted on the Over-the-Counter Bulletin Board (“OTCBB”) under the symbol "DORB." On March 26, 2008, the last quoted sale price for our common stock as reported on the OTCBB was $0.18 per share.

Investing in our common stock involves certain risks. See "Risk Factors" beginning on page 5 for a discussion of these risks.

One of the selling stockholders, Fusion Capital Fund II, LLC (“Fusion Capital”), is an "underwriter" within the meaning of the Securities Act of 1933, as amended. The other selling stockholders may be "underwriters" within the meaning of the Securities Act of 1933, as amended.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

DOR BioPharma, Inc.
850 Bear Tavern Road, Suite 201
Ewing, New Jersey 08628
(609) 538-8200

The date of this prospectus is April 11, 2008

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You should rely only on the information contained or incorporated by reference in this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with different information.

We have not authorized the selling stockholders to make an offer of these shares of common stock in any jurisdiction where the offer is not permitted.

You should not assume that the information in this prospectus or prospectus supplement is accurate as of any date other than the date on the front of this prospectus.

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FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements as defined in the Private Securities Reform Act of 1995. These forward-looking statements are often identified by words such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “contin and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to make certain that our cash expenditures do not exceed projected levels;
- our ability to obtain future financing or funds when needed;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- our ability to successfully obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;
- our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;
- our ability to patent, register and protect our technology from challenge and our products from competition;
- maintenance or expansion of our license agreements with our current licensors;
- maintenance of a successful business strategy;
- the FDA’s issuance of a not approvable letter in response to our NDA for orBec®
- orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- we are dependent on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;
- orBec® may not gain market acceptance; and
- others may develop technologies or products superior to our products.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

PROSPECTUS SUMMARY

The Company

We were incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines.

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

Our principal executive offices are located at 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628 and our telephone number is (609) 538-8200.

orBec®

Our lead therapeutic product, orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the Prescription Drug User Fee Act ("PDUFA"), the FDA was to complete its review of all materials related to orBec® by July 21, 2007. Additionally, on May 9, 2007, the Oncologic Drugs Advisory Committee ("ODAC") appointed by the FDA voted that the data supporting orBec® did not show substantial evidence of efficacy by a margin of 7 to 2 for the treatment of GI GVHD. The FDA was not bound by ODAC's recommendations, but it took the panel's advice into consideration when reviewing the NDA for orBec®.

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

On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an end of review conference with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well-designed, well-executed and provides clinically

and statistically meaningful findings; (2) we anticipate working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's special protocol assessment process; (3) the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study. Once we have agreement on the confirmatory protocol with the FDA, we expect to begin enrollment in the new confirmatory Phase 3 clinical program for the treatment of GI GVHD in the second half of 2008.

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

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

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

On July 12, 2007, we announced that patient enrollment had commenced in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic HCT with myeloablative conditioning regimens. The Phase 2 clinical trial is supported in part by an NIH grant awarded to the FHCRC. We will not receive any monetary benefit from this grant. The protocol is entitled “A Phase 2 study to evaluate the efficacy of oral beclomethasone dipropionate for prevention of acute GVHD after hematopoietic cell transplantation with myeloablative conditioning regimens.” The study will enroll a total of 138 patients with 92 subjects in the orBec® arm and 46 subjects in the placebo arm. The principal investigator of the trial is Paul Martin, M.D., of the FHCRC and a Professor of Medicine at Washington University. Patients will be treated with orBec® or placebo at the start of their conditioning regimen and will continue to be treated for 75 days after transplantation. The objective of the trial is to test the hypotheses that prophylactic administration of orBec® can prevent the incidence and/or reduce the severity of acute GVHD, therefore, decreasing the need for use of high dose systemic steroid treatment after allogeneic HCT. Completion of patient enrollment in this trial is targeted for the first half of 2009.

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

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

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

RiVax™

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

neutralizing antibodies as confirmed in subsequent animal studies.

BT-VACC™

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

The Offering

This prospectus relates to the offer and sale from time to time of up to 26,563,613 shares of our common stock by the selling stockholders, 881,112 shares of which were issued to seven of the selling stockholders in a private placement on February 14, 2008 and 354,722 shares of which were issued to two of the selling stockholders as compensation for consulting services rendered.

Fusion Capital, one of the selling stockholders under this prospectus, is offering for sale up to 25,327,778 shares of our common stock. Fusion Capital is not an affiliate of, and has no relation to, any of the other selling stockholders named herein. On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, an Illinois limited liability company. Under the agreement, Fusion Capital is obligated, under certain conditions, to purchase shares from us in an aggregate amount of $8.5 million from time to time over a 25-month period. We have sold 2,777,778 shares of common stock to Fusion Capital (together with a four-year warrant to purchase 1,388,889 shares of our common stock purchase that are not part of this offering) under the agreement for total proceeds of $500,000. Under the terms of the common stock purchase agreement, Fusion Capital has received a commitment fee consisting of 1,275,000 shares of our common stock. Also, we will issue to Fusion Capital an additional 1,200,000 shares as a commitment fee pro rata as we receive the $8.0 million of future funding. We issued 75,000 shares as a pro rata commitment fee in connection with the purchase by Fusion Capital of the $500,000 of our common stock. All 2,550,000 shares issued or to be issued to Fusion Capital as a commitment fee are being included in the offering pursuant to this prospectus. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement.

As of March 26, 2008, there were 100,299,378 shares outstanding (93,639,020 shares held by non-affiliates), excluding the 20 million shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of such 20 million shares that may be sold to Fusion Capital and are offered hereby were issued and outstanding as of the date hereof, the 20 million shares would represent approximately 17% of the total common stock outstanding, or approximately 18% of the non-affiliates shares outstanding, as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement.

We do not have the right to commence any additional sales of our shares to Fusion Capital until the Securities and Exchange Commission (“SEC”) has declared effective the registration statement of which this prospectus is a part. After the SEC has declared effective such registration statement, generally we have the right but not the obligation from time to time to sell our shares to Fusion Capital in amounts between $80,000 and $1.0 million depending on certain conditions. The registration statement was declared effective on April 4, 2008 and the conditions to commence funding were satisfied on April 11, 2008. We have the right to control the timing and amount of any sales of our shares to Fusion Capital. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale. Fusion Capital shall neither have the right nor the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below $0.10. The agreement may be terminated by us at any time at our discretion without any cost to us.

RISK FACTORS

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

Risks Related to our Industry

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

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

We have sufficient funds through our existing, biodefense grant facilities from the NIAID to finance our biodefense projects. On September 29, 2006, we announced that we had received approximately $5,300,000 in grants for the development of our biodefense programs. We estimate that the overhead revenue contribution from our existing NIH biodefense grants will generate an additional $850,000 over the next four quarters.

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

If the price of our stock is less than $0.10 per share, we cannot utilize the Fusion Capital facility, and, in such event, we may not be able to obtain additional required funding on terms satisfactory to us, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives.

If adequate financing is not obtained through our facility with Fusion Capital, we will require additional financing to sustain our operations and without it we may not be able to continue operations at present levels.

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

We only have the right to receive $80,000 per every three trading days under the agreement with Fusion Capital unless our stock price equals or exceeds $0.15, in which case the amount may be increased under certain conditions as the price of our common stock increases. We cannot require Fusion Capital to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.10. Since we initially registered 22,777,778 shares for sale by Fusion Capital pursuant to this prospectus (excluding the 2,550,000 commitment fee shares), the selling price of our common stock to Fusion Capital will have to average at least $0.37 per share for us to receive the maximum proceeds of $8.5 million without registering additional shares of common stock. Assuming a purchase price of $0.18 per share (the closing sale price of the common stock on March 26, 2008), proceeds to us would only be $4,100,000, which includes the $500,000 already received, unless we choose to register more than 22,777,778 shares (excluding the 2,550,000 commitment fee shares), which we have the right to do. Subject to approval by our board of directors, we have the right under the common stock purchase agreement to issue more than 22,777,778 (excluding the 2,550,000 commitment fee shares) shares to Fusion Capital. In the event we elect to issue more than the 22,777,778 (excluding the 2,550,000 commitment fee shares) shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC, although we currently have no present intention to register additional shares.

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

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

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

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

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

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

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

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

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

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

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

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

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

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There may be unforeseen challenges in developing our biodefense products.

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

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

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

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

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

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers

and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

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

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

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

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

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

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

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

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

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

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

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

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

able to compete successfully with our existing and future competitors.

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

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

Our stock price has fluctuated between January 1, 2004 through March 26, 2008, the per share price of our common stock ranged between a high of $1.58 per share to a low of $0.15 per share. As of March 26, 2008, our common stock

traded at $0.18. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock trades on the Over-the-Counter Bulletin Board.

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

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

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

Shareholders may suffer substantial dilution.

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

- warrants to purchase a total of approximately 30,900,000 shares of our common stock at a current weighted average exercise price of approximately $0.67;

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

- options to purchase approximately 10,250,000 shares of our common stock of a current weighted average exercise price of approximately $0.44.

During 2008, outstanding warrants to purchase approximately 10,000,000 shares of our common stock will expire. By April 2009, outstanding warrants to purchase a total of approximately 20,000,000 shares of our common stock will expire.

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

Shareholders are also subject to the risk of substantial dilution to their interests as a result of our issuance of shares under the common stock purchase agreement with Fusion Capital. Under the agreement, we have the right, but not

the obligation, under certain conditions, to sell shares of common stock to Fusion Capital in an aggregate amount of $8.5 million from time to time over a 25 month period. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale.

We already have sold 2,777,778 shares of common stock to Fusion Capital (together with a warrant to purchase 1,388,889 shares of our common stock) under the agreement for total proceeds of $500,000. In addition to the shares already sold to Fusion Capital, 20 million shares that may be sold to Fusion Capital are included in the registration statement of which this prospectus is a part. We may ultimately sell all, some or none of the 20 million shares of common stock. If such 20 million shares were issued and outstanding as of March 26, 2008, the 20 million shares would have represented approximately 20% of the total outstanding common stock.

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

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

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

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital under this prospectus is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 25,327,778 shares registered for sale by Fusion Capital in this offering are expected to be freely tradable. It is anticipated that the 20 million shares offered by Fusion Capital will be sold over a period of up to 25 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the 20 million shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock under this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

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

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

Fusion Capital's purchase and sale into the market of our common stock could cause our common stock price to decline due to the additional shares available in the market, particularly in light of the relatively thin trading volume of our common stock. The market price of our common stock could decline given our minimal average trading volume compared to the number of shares potentially issuable to Fusion Capital, and the voting power and value of your investment would be subject to continual dilution if Fusion Capital purchases the shares and resells those shares into

the market, although there is no obligation for Fusion Capital to sell such shares. Any adverse affect on the market price of our common stock would increase the number of shares issuable to Fusion Capital which would increase the potential dilution of your investment.

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BUSINESS

Overview

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

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

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

BioTherapeutics Overview

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

statistically significant survival advantage in comparison to placebo at 200 days post-transplantation (p-value 0.0139) and at one year post-randomization (p-value 0.04).

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

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

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

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

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

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

BioDefense Overview

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

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

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

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

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

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

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

BioTherapeutics Division

orBec®

Our lead therapeutic product, orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. We filed an NDA on September 21, 2006 for orBec® with the FDA for the treatment of GI GVHD. The NDA was accepted on November 21, 2006, and in accordance with the Prescription Drug User Fee Act ("PDUFA"), the FDA was to complete its review of all materials related to orBec® by July 21, 2007. Additionally, on May 9, 2007, the Oncologic Drugs Advisory Committee ("ODAC") appointed by the FDA voted that the data supporting orBec® did not show substantial evidence of efficacy

by a margin of 7 to 2 for the treatment of GI GVHD. The FDA was not bound by ODAC's recommendations, but it took the panel's advice into consideration when reviewing the NDA for orBec®.

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

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

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

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

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

On July 12, 2007, we announced that patient enrollment had commenced in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic HCT with myeloablative conditioning regimens. The Phase 2 clinical trial is supported in part by an NIH grant awarded to the FHCRC. We will not receive any monetary benefit from this grant. The protocol is entitled "A Phase 2 study to evaluate the efficacy of oral beclomethasone dipropionate for prevention of acute GVHD after hematopoietic cell transplantation with myeloablative conditioning regimens." The study will enroll a total of 138 patients with 92 subjects in the orBec® arm and 46 subjects in the placebo arm. The principal investigator of the trial is Paul Martin, M.D., of the FHCRC and a Professor of Medicine at Washington University. Patients will be treated with orBec® or placebo at the start of their conditioning regimen and will continue to be treated for 75 days after transplantation. The objective of the trial is to test the hypotheses that prophylactic administration of orBec® can prevent the incidence and/or reduce the severity of acute GVHD, therefore, decreasing the need for use of high dose systemic steroid treatment after allogeneic HCT. Completion of patient enrollment in this trial is targeted for the first half of 2009.

On September 12, 2007, we announced that our academic partner, FHCRC, received a $1 million grant from the NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®)

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

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

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

orBec® Comprehensive Long-Term Mortality Results

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

200 Days Post Transplantation Mortality Results

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

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

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A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the pivotal Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significantly different. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

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

Safety and Adverse Events

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

Commercialization and Market

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

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

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

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

Cost and Development of our Programs

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

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

Research and Development

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

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

About Graft-versus-Host Disease

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

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

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

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

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

Future Potential Indications of orBec® and Oral BDP

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

Other Products in BioTherapeutics Pipeline

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

LPMTM - Leuprolide

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

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

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

We expect to validate the LPM platform technology using leuprolide as the target peptide. We expect to perform a Phase 1 PK study with a version of LPM that prolongs the absorption of leuprolide and results in high relative bioavailability. An oral version of leuprolide may also provide a significant advantage over the currently marketed "depot" formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide sales of approximately $1.8 billion in 2006. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

Research and Development

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

Cost and Development analysis for LPM™ Leuprolide

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

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

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OraprineTM

We anticipate that an orally administered version of the immunosuppressant drug azathioprine may have a significant role in treating inflammatory diseases of the oral cavity. Further, an orally administered drug may provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine that would have utility in elderly patients. OraprineTM is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the United States as Imuran®. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Joel Epstein at the University of Washington that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from GVHD. Oral GVHD can occur in up to 70% of patients who have undergone bone marrow/stem cell transplantation despite treatment with other immunosuppressive drugs such as prednisone, methotrexate, tacrolimus, and cyclosporine. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient.

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

Research and Development

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

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

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

LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs

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

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BioDefense Programs

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

RiVaxTM - Ricin Toxin Vaccine

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

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

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

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

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

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

Research and Development

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

Cost and Development analysis for RiVax™

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

BT-VACCTM - Botulinum Toxin Vaccine

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

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

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

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

Research and Development

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

Cost and Development analysis for BT-VACC™

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

Strategy for development of BioDefense products

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

BioTherapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of Acute GI GVHD	Phase 3 confirmatory trial to be initiated in 2008. MAA filed and under review
orBec®	Prevention of Acute GVHD	Phase 2 trial enrolling
orBec®	Treatment of Chronic GI GVHD	Phase 2 to be initiated in 2008
Oral BDP	Radiation Enteritis and Radiation Exposure	Phase 2 to be initiated in 2008
LPMTM – Leuprolide	Endometriosis and Prostate Cancer	Phase 1 to be initiated in 2008

OraprineTM	Oral lesions resulting from Graft-versus-Host Disease	Phase 1/2 ro be initiated in 2009
LPETM and PLPTM Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

Biodefense Products

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

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The Drug Approval Process

General

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

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

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

Clinical trials are normally done in three Phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

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

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

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

Marketing Strategies

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

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

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.

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Biodefense Vaccine Competition

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

orBec® Competition

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

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

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

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.

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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®.

Ricin Vaccine Intellectual Property

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

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

Botulinum Toxin Vaccine Intellectual Property

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

Employees

As of March 26, 2008, we had seven full-time employees, three of whom are Ph.Ds.

Research and Development Spending

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

Description of Property

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

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 28, 2005, we entered into a letter of intent to acquire Gastrotech Pharma A/S (Gastrotech), a private, Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. On January 26, 2006, we advised Gastrotech that we were not renewing our letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1,000,000 breakup fee in the event either party notified the other of its intention not to proceed with the transaction. The attorney representing Gastrotech has advised us that if we are not willing to comply with the terms in the letter of intent, we will be in material breach of our obligations under the letter of intent and will be obligated to pay Gastrotech a break-up fee of $1,000,000. As of the date of this 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 we do not owe Gastrotech any break-up fee pursuant to not renewing the letter of intent to acquire Gastrotech.

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 prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Forward-Looking Statements."

Business Overview and Strategy

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

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

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

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Critical Accounting Policies

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

Intangible Assets

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

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

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

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

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

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

Research and Development Costs

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

Revenue Recognition

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

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Material Changes in Results of Operations

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

For the year ended December 31, 2007, we had grant revenues of $1,258,017 as compared to $2,313,020 in the 12 months ended December 31, 2006, a decrease of $1,055,003, or 46%. In 2006 compared to 2007, our progress on the grant had exceeded the original schedule, which accelerated the milestone revenues that were recorded in the first quarter of 2006. We also incurred expenses correlated to the revenue in 2007 and 2006 of $943,385 and $1,965,074, respectively, a decrease of $1,021,689, or 52%. These costs relate to payments made to subcontractors and universities in connection with the grants.

The gross profit for the 12 months ended December 31, 2007 was $314,632 as compared to $347,946 in the 12 months ended December 31, 2006, a decrease of $33,314, or 10%. This was due to the decreased grant revenues in the first quarter ended 2007 that were eligible for the F&A rate as well as the expected decrease in the final F&A rate.

Research and development spending decreased $538,549, or 15%, to $3,099,944, for the 12 months ended December 31, 2007 as compared to $3,638,493 for the corresponding period ended December 31, 2006. In the third quarter of 2007, a majority of expenses were related to preparation of FDA and European regulatory matters. During the fourth quarter of 2007, our research and development expenses were greatly reduced as a result of the end of FDA's review of our NDA for orBec®.

In-process research and development expenditures were $0 for the 12 months ended December 31, 2007, a decrease of 100% as compared to $981,819 for the same period ended December 31, 2006. This decrease was due to the purchase acquisition in 2006 of all of the outstanding common stock of Enteron that the Company did not already own.

Impairment expense for intangibles was $0 for the 12 months ended December 31, 2007, a decrease of 100% as compared to $816,300 for the same period ended December 31, 2006. This was due to the impairment of the Southern Research Institute/Brookwood Pharmaceuticals license of microsphere technology.

Stock based compensation expenses for research and development increased $10,733, or 5%, to $230,668 for the 12 months ended December 31, 2007, as compared to $219,895 for the corresponding period ended December 31, 2006.

Stock based compensation expenses for general and administrative increased $109,486, or 32%, to $446,773 for the 12 months ended December 31, 2007, as compared to $337,287 for the corresponding period ended December 31, 2006.

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

Interest income for the 12 months ended December 31, 2007 was $164,847 as compared to $41,510 for the 12 months ended December 31, 2006, representing an increase of $123,337, or 297%. This increase is due to a higher cash balance in 2007 as compared to 2006.

Interest expense for the 12 months ended December 31, 2007 was $1,020 as compared to $5,308 for the 12 months ended December 31, 2006, a decrease of $4,288, or 81%. This decrease was the result of lower balances that were

short-term financed for insurance premiums due and therefore less interest was accrued and paid.

For the 12 months ended December 31, 2007, we had a net loss of $6,164,643 as compared to a $8,163,346 net loss for the 12 months ended December 31, 2006, a decrease of $1,998,703, or 24%. This decrease in the net loss is primarily attributed to higher costs in 2006 for: regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®; the in-process research and development expense of $981,819 for acquiring all of the outstanding common stock of Enteron that the Company did not already own, the impairment expense for intangibles of $816,300, and the dilution expense taken for stock issued to investors from the April 2006 private placement in the amount of $308,743.

Financial Condition

Cash and Working Capital

As of December 31, 2007, we had cash of $2,220,128, as compared to $119,636 as of December 31, 2006. As of March 26, 2008, we had cash of approximately $2,000,000. As of December 31, 2007, we had working capital of $1,243,638, as compared to negative working capital of $2,211,387 as of December 31, 2006, representing an increase of $3,455,025. For the 12 months ended December 31, 2007, our cash used in operating activities was approximately $6,000,000, compared to $4,100,000 for the corresponding period ended December 31, 2006.

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

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

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

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Expenditures

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

The table below details our costs for the 12 months ended December 31, 2007 and December 31, 2006 by program.

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

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Debt

We had no notes payable at December 31, 2007 or at December 31, 2006. 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, 2007, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

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

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

Equity Transactions

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.5 million over approximately a 25-month period. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. We issued an additional 75,000 shares of common stock as a commitment fee in connection with the purchase of $500,000 of our common stock. If our stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of our common stock increases. We cannot require Fusion Capital to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.10 per share.

On February 14, 2008, we completed the sale of 881,111 shares of our common stock to institutional and other accredited investors for an aggregate purchase price of approximately $158,600. The investors also received four year warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $22 per share.

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

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction's dilutive nature, all investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders who still held shares of the Company's common stock from that placement were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. Neither these investors, nor any other investors, hold any further anti-dilution rights. Because no agreement was reached by March 1, 2007, we were obligated to return the $2 million to Sigma-Tau by April 30, 2007. On June 1, 2007, we returned the $2 million to Sigma Tau.

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

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

In February 2005, we increased our cash position by the issuance and sale of 8,396,100 shares of our common stock at $0.45 per share in a private placement to institutional investors. These investors also received warrants to purchase 6,297,075 shares of our common stock at an exercise price of $0.505 per share. The proceeds after related expenses and closing costs were approximately $3.5 million. We do not believe these warrants required application of SFAS No. 133. We determined this based on two interpretations of SFAS No. 133. First, the warrants have no initial allocable investment (paragraph 8 of SFAS No. 133). All three classes of warrants in question were issued in

connection with private placements whose participants purchased units that included upfront shares as well as a certain percentage of out-of-the-money warrants deemed to have some future benefit. Second, all three classes of warrants are “regular-way” security trades as described in paragraph 10 of SFAS No. 133. Once exercised for cash, the warrant holders are issued common stock shares within three business days as required by public exchanges.

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

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

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

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

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

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

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DIRECTORS AND EXECUTIVE OFFICERS

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

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

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

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

Christopher J. Schaber, Ph.D., has been our President and Chief Executive Officer and a director since August 2006. Prior to joining us, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, preclinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising in excess of $150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute

Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, his M.S. in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. in Pharmaceutical Sciences from The Union Graduate School.

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

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

EXECUTIVE COMPENSATION

Summary Compensation

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

Summary Compensation Table

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

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

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

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

Potential Issuance of Shares

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

Employment and Severance Agreements

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

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

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

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

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

if such event occurs.

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

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

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

Outstanding Equity Awards at Fiscal Year-End

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

Outstanding Equity Awards at Fiscal Year-End

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

Compensation of Directors

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

Director Compensation

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

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

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

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

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The table below provides information regarding the beneficial ownership of the common stock as of March 24, 2008 of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

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

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* Indicates less than 1%.

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

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

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

(3) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 1,465,625 shares of common stock and warrants to purchase 90,220 shares of common stock within 60 days of March 24, 2008. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

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

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

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Equity Compensation Plan Information

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

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

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

THE FUSION TRANSACTION

General

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, an Illinois limited liability company. Under the agreement, Fusion Capital is obligated, under certain conditions, to purchase shares from us in an aggregate amount of $8.5 million from time to time over a 25 month period. We have sold 2,777,778 shares of common stock to Fusion Capital (together with a warrant to purchase 1,388,889 shares of our common stock purchase that are not part of this offering) under the agreement for total proceeds of $500,000. Under the terms of the common stock purchase agreement, Fusion Capital has received a commitment fee consisting of 1,275,000 shares of our common stock. Also, we will issue to Fusion Capital an additional 1,200,000 shares as a commitment fee pro rata as we receive the $8.0 million of future funding. We issued 75,000 shares as a pro rata commitment fee in connection with the purchase by Fusion Capital of $500,000 of our common stock. All 2,550,000 shares issued or to be issued to Fusion Capital as a commitment fee are being included in the offering pursuant to this prospectus. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement.

As of March 26, 2008, there were 100,299,378 shares outstanding (93,639,020 shares held by non-affiliates), excluding the 20 million shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us and the 1,200,000 shares that we will issue to Fusion Capital as a commitment fee as we receive the $8.0 million of future funding. If all of such 20 million shares that may be sold to Fusion Capital and that are offered hereby were issued and outstanding as of the date hereof, the 20 million shares would represent approximately 17% of the total common stock outstanding, or 18% of the non-affiliates shares outstanding, as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement.

We do not have the right to commence any additional sales of our shares to Fusion Capital until the SEC has declared effective the registration statement of which this prospectus is a part of. After the SEC has declared effective such registration statement, generally we have the right but not the obligation from time to time to sell our shares to Fusion Capital in amounts between $80,000 and $1.0 million depending on certain conditions. The registration statement was declared effective on April 4, 2008 and the conditions to commence funding were satisfied on April 11, 2008. We have the right to control the timing and amount of any sales of our shares to Fusion Capital. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale. Fusion Capital shall neither have the right nor the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below $0.10. The agreement may be terminated by us at any time at our discretion without any cost to us.

Purchase of Shares Under the Common Stock Purchase Agreement

Under the common stock purchase agreement, on any trading day selected by us, we may direct Fusion Capital to purchase up to $80,000 of our common stock. The purchase price per share is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the average of the three lowest closing sale prices of our common stock during the 12 consecutive trading days prior to the date of a purchase by Fusion Capital.

The purchase price will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading days used to compute the purchase price. We may direct Fusion Capital to make multiple purchases from time to time in our sole discretion; no sooner then every third business day.

Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price ("floor price") of $0.10. However, Fusion Capital shall have neither the right nor the obligation to purchase any shares of our common stock in the event that the purchase price would be less the floor price.

Our Right to Increase the Amount to be Purchased

In addition to purchases of up to $80,000 from time to time, we may also from time to time elect on any single business day selected by us to require Fusion Capital to purchase our shares in an amount up to $100,000 provided that our share price is not below $0.15 during the three business days prior to and on the purchase date. We may increase this amount to up to $250,000 if our share price is not below $0.25 during the three business days prior to and on the purchase date. This amount may also be increased to up to $500,000 if our share price is not below $0.50 during the three business days prior to and on the purchase date. This amount may also be increased to up to $1.0 million if our share price is not below $1.00 during the three business days prior to and on the purchase date. We may direct Fusion Capital to make multiple large purchases from time to time in our sole discretion; however, at least two business days must have passed since the most recent large purchase was completed. The price at which our common stock would be purchased in this type of larger purchases will be the lesser of (i) the lowest sale price of our common stock on the purchase date and (ii) the lowest purchase price (as described above) during the previous ten business days prior to the purchase date.

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to the Company upon the occurrence of any of the following events of default:

- the effectiveness of the registration statement of which this prospectus is a part of lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereby and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of three consecutive business days;

- the de-listing of our common stock from our principal market provided our common stock is not immediately thereafter trading on the Nasdaq Global Market, the Nasdaq Capital Market, the New York Stock Exchange or the American Stock Exchange;

- the transfer agent's failure for five business days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the common stock purchase agreement;

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any material breach of the representations or warranties or covenants contained in the common stock purchase agreement or any related agreements which has or which could have a material adverse effect on us subject to a cure period of five business days; or

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the common stock purchase agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the common stock purchase agreement.

Effect of Performance of the Common Stock Purchase Agreement on Our Stockholders

All 25,327,778 shares registered in connection with the Fusion Capital transaction are expected to be freely tradable. It is anticipated that shares registered in connection with the Fusion Capital transaction will be sold over a period of up to 25 months from the date of this prospectus. The sale by Fusion Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Fusion Capital may ultimately purchase all, some or none of the 20 million shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 20 million shares of our common stock (excluding the 2,777,778 shares issued to Fusion Capital upon execution of the common stock purchase agreement, the 1,388,889 shares underlying the warrant, and the 2,550,000 commitment fee shares). The number of shares ultimately offered for sale by Fusion Capital under this prospectus is dependent upon the number of shares purchased by Fusion Capital under the agreement. The following table sets forth the amount of proceeds we would receive from Fusion Capital from the sale of shares at varying purchase prices, not including the $500,000 we already received for the sale of 2,777,778 shares:

Assumed Average Purchase Price	Number of Shares to be Issued if Full Purchase	Percentage of Outstanding Shares After Giving Effect to the Issuance to Fusion Capital (1)	Proceeds from the Sale of Up to 20 Million Shares to Fusion Capital Under the Common Stock Purchase Agreement
$0.10	20,000,000	17%	$2,000,000
$0.18(2)	20,000,000	17%	$3,600,000
$0.25	20,000,000	17%	$5,000,000

$0.40	20,000,000	17%	$8,000,000
$0.50	16,000,000	14%	$8,000,000
$0.60	13,333,333	12%	$8,000,000

(1) The denominator is based on 100,299,378 shares outstanding as of March 26, 2008, which includes the 4,052,778 shares previously issued to Fusion Capital and the number of shares set forth in the adjacent column. The numerator is based on the number of shares issuable under the common stock purchase agreement at the corresponding assumed purchase price set forth in the adjacent column.

(2) Closing sale price of our shares on March 26, 2008.

Commitment Shares Issued to Fusion Capital

Unless an event of default occurs, the commitment shares must be held by Fusion Capital until the earlier of (i) 25 months from the date of the common stock purchase agreement or (ii) the date the common stock purchase agreement is terminated; however this restriction does not apply in the event that we do not commence sales of stock to Fusion Capital prior to June 1, 2008.

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SELLING STOCKHOLDERS

The following table presents information as of March 26, 2008 and sets forth the number of shares of common stock owned by the selling stockholders. The following table assumes that all of the shares being registered pursuant to this prospectus will be sold. The selling stockholders are not making any representation that any shares covered by this prospectus will be offered for sale.

Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us except that, on January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital for the purchase of up to $6 million of our common stock over a 15 month period. Under that agreement we sold 329,540 of our common shares to Fusion Capital over an approximately 15 month period for proceeds of approximately $125,000. That agreement expired pursuant to its terms and we cannot sell any additional shares to Fusion Capital under that agreement.

Name of Selling Stockholders	Number of Shares of Common Stock Owned Before the Offering (1)	Percent of Common Stock Owned Before the Offering	Shares Available for Sale Under This Prospectus (1)	Number of Shares of Common Stock To Be Owned After Completion of the Offering	Percent of Common Stock to be Owned After Completion of the Offering
Fusion Capital II, LLC (2)	4,127,778	4.1 %	25,327,778	-	0%
Bernard D. Noble	377,778	*	277,778	100,000	*
Bear Stearns Corp. Custodian For Lloyd R. Brokaw IRA	182,000	*	125,000	57,000	*
Little Gem Life Sciences Fund LLC (3)	120,000	*	120,000	-	0%
Vasili Myrianthopoulos	144,611	*	111,111	33,500	*
Steven Mark	225,000	*	125,000	100,000	*
Robin Mirianthopoulos	66,667	*	66,667	-	0%
Joan Orwen	55,556	*	55,556	-	0%
IBIS Consulting (4)	7,500	*	7,500	-	0%
Numoda Corporation (5)	347,222	*	347,222	-	0%

* Less than 1%

** Percentage of ownership is based on 100,299,378 shares of common stock outstanding as of March 26, 2008.

(1) As of the date hereof, we have issued 2,777,778 shares of our common stock to Fusion Capital under the common stock purchase agreement and 1,350,000 shares of our common stock as a commitment fee. Fusion Capital may acquire up to an additional 20 million shares from purchases under the common stock purchase agreement and an additional 1,200,000 shares as a commitment fee pro rata as we receive the $8.0 million of future funding, all of which are included in the offering pursuant to this prospectus.

(2) Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and disposition power over the shares being offered by Fusion Capital under this prospectus.

(3) Jeffrey Benison is the principal of Little Gem Life Sciences Fund LLC, and is deemed to be beneficial owner of all of the shares of common stock owned by Little Gem Life Sciences Fund LLC. Mr. Benison has sole voting and sole disposition power over the shares being offered by Little Gem Life Sciences Fund LLC under this prospectus.

(4) Dina Lyaskovets is the principal of IBIS Consulting, and is deemed to be beneficial owner of all of the shares of common stock owned by IBIS Consulting. Ms. Lyaskovets has sole voting and sole disposition power over the shares being offered by IBIS Consulting under this prospectus.

(5) Mary Schaheen is the principal of Numoda Corporation, and is deemed to be beneficial owner of all of the shares of common stock owned by Numoda Corporation. Mrs. Schaheen has sole voting and sole disposition power over the shares being offered by Numoda Corporation under this prospectus.

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USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to $8.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement, excluding the $500,000 we already received. We plan to use the proceeds from this financing to: (a) design new clinical trials in GI GVHD; (b) seek a development and marketing partner for orBec® for territories both inside and outside of the U.S.; (c) prepare for the potential marketing approval of orBec® by the EMEA; (d) conduct a prophylactic use clinical trial of orBec® for the prevention of GI GVHD; (e) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis and Crohn's disease; (f) reinitiate development including manufacturing of our other biotherapeutics products namely LPMTM-Leuprolide, and OraprineTM; (g) secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts, and procurements; (h) explore acquisition strategies under which we may be acquired by another company with oncologic or gastrointestinal symmetry; (i) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area; and (j) acquire or in-license new clinical-stage compounds for development.

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

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholders. The common stock may be sold or distributed from time to time by the selling stockholders directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholders and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

One of the selling stockholders, Fusion Capital, is an "underwriter" within the meaning of the Securities Act. The other selling stockholders may be deemed "underwriters" within the meaning of the Securities Act.

Neither we nor the selling stockholders can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholders, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholders, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify the selling stockholders and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

After the effective date of the registration statement, the selling stockholders, other than Fusion Capital, may engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades. Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the common stock purchase agreement.

We have advised the selling stockholders that while they are engaged in a distribution of the shares included in this prospectus they are required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by the selling stockholders.

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DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 255,000,000 shares of capital stock, of which 250,000,000 shares are common stock, par value $.001 per share, 4,600,000 shares are preferred stock, par value $0.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $0.05 per share, and 200,000 shares are Series C Convertible Preferred Stock, par value $0.05 per share. As of March 26, 2008, there were issued and outstanding 100,299,378 shares of common stock, options to purchase approximately 10,349,839 shares of common stock and warrants to purchase approximately 30,598,230 shares of common stock. The amount outstanding excludes the $8.5 million of common stock that may be issued to Fusion Capital.

Common Stock

Holders of our common stock are entitled to one vote for each share held in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting in the election of directors. Holders of common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the corporation, holders of common stock are to share in all assets remaining after the payment of liabilities. Holders of common stock have no pre-emptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. The rights of the holders of the common stock are subject to any rights that may be fixed for holders of preferred stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 4,600,000 shares of preferred stock with designations, rights, and preferences as may be determined from time to time by the board of directors. The board of directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock with dividend, liquidation, conversion, voting or other rights, including the right to issue convertible securities with no limitations on conversion, which could adversely affect the voting power or other rights of the holders of our common stock, substantially dilute a common stockholder’s interest and depress the price of our common stock.

No shares of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock are outstanding.

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MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted 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 quoted on the website of the OTCBB, for the period from January 1, 2006 through December 31, 2007. Until April 18, 2006, our common stock was listed on the American Stock Exchange. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

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

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of March 26, 2008, the last reported price of our common stock was $0.18 per share. The OTCBB price quoted reflects inter-dealer prices, without retail mark-up, mark down or commission, and may not represent actual transactions. We have approximately 1,071 registered holders of record.

Dividend Policy

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

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DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Section 102(b)(7) of the Delaware General Corporation Law allows companies to limit the personal liability of its directors to the company or its stockholders for monetary damages for breach of a fiduciary duty. Article IX of the Company's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Company as follows:

"A Director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Company's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

EXPERTS

The audited consolidated financial statements of DOR BioPharma, Inc. and subsidiaries included in the Registration Statement have been audited by Sweeney, Gates & Co., an independent registered public accounting firm, for the years ended December 31, 2007 and 2006, as set forth in their report appearing herein. Such financial statements have been so included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the shares of our common stock offered by the selling stockholders will be passed upon by the law firm of Edwards Angell Palmer & Dodge LLP, West Palm Beach, Florida.

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DOR BIOPHARMA, INC. AND SUBSIDIARIES

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