DOR BIOPHARMA INC
Form SB-2
May 10, 2006

As filed with the Securities and Exchange Commission on May 10, 2006.
Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM SB-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DOR BioPharma, Inc.

(Name of small business issuer as specified in its charter)

Delaware	**2834**	**41-1505029**
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

DOR BioPharma, Inc.
Lincoln Building, 1691 Michigan Ave
Miami, Florida 33139
(305) 534-3383
(Address and telephone number of principal executive offices and principal place of business)

Michael T. Sember
President and Chief Executive Officer
DOR BioPharma, Inc.
Lincoln Building, 1691 Michigan Ave
Miami, Florida 33139
(305) 534-3383
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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with copies to:
Leslie J. Croland, Esq.
Edwards Angell Palmer & Dodge LLP
350 East Las Olas Blvd., Suite 1150
Fort Lauderdale, Florida 33334-3607
(954) 727-2600

Approximate date of commencement of proposed sale to the public: From time to time, at the discretion of the selling stockholder, after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee(2)
Common Stock, $.001 par value per share (3)	**30,629,819**	$0.32	$9,801,542.00	$1,048.76

(1) Includes up to 14,461,673 shares of the Registrant's common stock issuable upon exercise of warrants, and 13,099,964 shares of the Registrant's common stock, issued to certain of the Selling Stockholders, as defined in the accompanying prospectus, on April 10, 2006, and 3,068,183 shares of the Registrant's common stock issued to certain Selling Stockholders as the result of a merger on May 10, 2006. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), to the extent additional shares of Registrant's common stock may be issued or issuable as a result of a stock split, stock dividend or other distribution declared at any time by the Registrant while this registration statement is in effect, this registration statement is hereby deemed to cover all such additional shares of common stock.
(2) Estimated solely for purposes of calculating the registration fee according to Rule 457(c) under the Securities Act of 1933, as amended, on the basis of the average of the high and low prices of the Registrant's common stock reported on the Over-The-Counter Bulletin Board on May 5, 2006.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this

Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED May 10, 2006

PROSPECTUS

DOR BioPharma, Inc.

30,629,819 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 30,629,819 shares of our common stock by the selling stockholders named in this prospectus in the section “Selling Stockholders,” including their pledgees, assignees and successors-in-interest, whom we collectively refer to in this document as the “Selling Stockholders.” We completed a stock purchase transaction pursuant to which we issued to certain of the Selling Stockholders an aggregate of 13,099,964 shares of our common stock and warrants to purchase up to an aggregate of 13,099,964 shares of common stock (the “Purchased Warrants”). In connection with the stock purchase transaction, we issued to two of the Selling Stockholders, as a broker’s fee, cash in the amount of $192,750 and warrants to purchase up to an aggregate of 1,361,708 shares of our common stock (together with the Purchased Warrants, the “Warrants”). In addition, 3,068,183 shares of our common stock are being registered for certain Selling Shareholders who received the shares as a result of a merger of one of our subsidiaries. The common stock offered by this prospectus shall be adjusted to cover any additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions. 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 May 5, 2006, the last reported sale price for our common stock as reported on the OTCBB was $0.32 per share.

Investing in our common stock involves certain risks. See "Risk Factors" beginning on page 6 for a discussion of these risks.

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.
Lincoln Building, 1691 Michigan Ave
Miami, Florida 33139
(305) 534-3383

The date of this prospectus is _____, 2006

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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 stockholder 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.

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 not considering orBec® approvable based upon existing studies because orBec® did not achieve statistical significance in its primary endpoint in the pivotal Phase III clinical study (i.e. a p-value of less than or equal to 0.05);
- orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, if required, 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 are a research and development biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of gastrointestinal Graft-versus-Host Disease, "GVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of gastrointestinal GVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs when resources permit; and (j) acquire or in-license new clinical-stage compounds for development.

Our principal executive offices are located at Lincoln Building, 1691 Michigan Ave., Miami, Florida 33139 and our telephone number is 305-534-3383.

orBec®

Our goal is to file an NDA with the FDA for orBec® for the treatment of gastrointestinal GVHD in the second quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GVHD to be between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

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

RiVax™

The development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. Our academic partner, The University of Texas Southwestern led by Dr. Ellen Vitetta, recently completed a Phase I safety and immunogenicity trial of RiVax™ in human volunteers. The results of the Phase I safety and immunogenicity dose-escalation study indicate that the vaccine is well tolerated and induces antibodies in humans that neutralize ricin toxin. The outcome of the study was recently published in the online edition of the Proceedings of the National Academy of Sciences. In January of 2005, we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the second milestone of

fermentation and downstream process development under their development and manufacturing agreement.

Botulinum Programs

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal 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. Our preclinical data to date demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date, much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for, and intend to continue to apply for, research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™, a high yield expression system based on *Pseudomonas fluorescens.* Up to this point we have successfully demonstrated successful high expression of soluble material from all three Hc50 vaccine candidates.

Botulinum Toxic Therapeutics

In 2005, we entered into an agreement with Blue Dolphin, LLC, a firm specializing in rational drug development, to apply computer-aided design to the discovery of small molecule drugs to counter Botulinum toxin exposure. Under the agreement, Blue Dolphin is exploring novel drug-like inhibitors of Botulinum toxin by targeting a new site on the toxin's structure. Candidate molecules will be modeled for structural and chemical fit to the target site on the toxin using computer aided discovery techniques. The best fitting molecules will be experimentally tested for their effectiveness in treating Botulinum toxin exposure. By focusing on the structure of the Botulinum toxin, as opposed to derivatives of previously known inhibitors, this "virtual screening" will allow DOR to target new parts of the toxin with new candidate inhibitors. To date, we have identified several lead inhibitors. Planned studies will focus on initial profiling of hits and validation testing for activity against botulinum toxin exposure, in addition to investigating the mechanism of action of confirmed quality hits.

We will apply for research grants and contracts from the U.S. government to continue development of these programs. The goal of our biodefense programs is to supply the United States government with qualified countermeasures that can protect citizens against ricin toxin and botulinum toxin exposure.

Recent Developments

On October 28, 2005, we entered into a binding 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 the letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1 million break-up fee in the event a party notifies the other of its intention not to proceed with the transaction. On January 30, 2006, we were advised by the attorney representing Gastrotech that if we were not willing to comply with the terms of the letter of intent, we would be in material breach of our obligations under the letter of intent and would be obligated to pay Gastrotech a break-up fee of $1 million. Our position is that we do not owe Gastrotech such break-up fee.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over approximately a 15-month period, subject to earlier termination at our discretion. We have sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not sell any additional shares to Fusion Capital until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when we resume selling stock to Fusion Capital, we may elect to sell less of our common stock than the daily amount, and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock to Fusion Capital based upon the future market price of the common stock. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. Under the terms of the common stock purchase agreement, we issued to Fusion Capital 450,000 shares of our common stock as a partial commitment fee upon entering into the agreement. Fusion Capital also received an additional 450,000 commitment shares.

On April 10, 2006, we completed the sale of an aggregate of 13,099,964 shares of our common stock to institutional and other accredited investors for an aggregate 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. Pursuant to a registration rights agreement, we agreed to file this registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

On May 10, 2006, we completed a merger pursuant to which our subsidiary, Enteron Pharmaceuticals, Inc. ("Enteron"), the common stock of which we held 89.13% prior to the merger, was merged into our wholly-owned subsidiary. Pursuant to this transaction, we issued 3,068,183 shares of our common stock to the former shareholders of Enteron ("Enteron Shareholders") in exchange for all of the outstanding common stock of Enteron that we did not already own.

As of May 5, 2006, there were 65,395,814 shares outstanding, including the 13,099,964 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus, including the 14,461,672 shares of our common stock underlying the Warrants, represent approximately 37% of the total common stock outstanding as of May 5, 2006, assuming such Warrants were fully exercised and the shares issued to the Enteron Shareholders were already issued.

The Selling Stockholders may sell these shares in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of shares by the Selling Stockholders.

We are also registering for sale any additional shares of common stock which may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

Risk Factors

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Also, you should be aware that the risks and uncertainties described below are not the only ones we face. 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 and we may be unable to continue our operations.

We are a company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2006, we had approximately $328,109 in cash available. On April 10, 2006, we completed the sale of an aggregate of 13,099,964 shares of our common stock to institutional and other accredited investors for an aggregate purchase price of $3,630,000. On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over approximately a 15-month period, subject to earlier termination at our discretion. We have sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not sell any additional shares to Fusion Capital without the prior consent of Iroquois until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when we resume selling stock to Fusion Capital, we may elect to sell less of our common stock than the daily amount, and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock to Fusion Capital based upon the future market price of the common stock. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.12. Since we initially registered 9,000,000 shares for sale by Fusion Capital pursuant to this prospectus (excluding the 900,000 commitment fee shares and 62,500 expense reimbursement shares that we have registered), the selling price of our common stock to Fusion Capital will have to average at least $0.67 per share for us to receive the maximum proceeds of $6.0 million without registering additional shares of common stock. Assuming a purchase price of $0.32 per share (the closing sale price of the common stock on May 5, 2006), proceeds to us would only be $2,880,000 unless we choose to register more than 9,962,500 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 9,962,500 shares to Fusion Capital. In the event we elect to issue more than 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the U.S. Securities and Exchange Commission. Based on our budgetary projections of $3,700,000 over the next 12 months, this facility, if we are able to utilize it per the restriction imposed by our April 2006 private placement, will allow us to continue and maintain operations into the 2nd quarter of 2007. In addition, our existing NIH biodefense grant facilities provide us with significant overhead contributions to continue to operate and manage our business. We estimate that the overhead revenue contribution from our existing NIH biodefense grants will generate an additional $550,000 over the next four quarters. The Company also has several other grant applications currently under review

that would allow the Company to significantly expand the pace and scope of development of its biodefense programs as well as make additional significant contributions to overhead.

All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through March 31, 2006, we had expended approximately $13,800,000 developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $5.0 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our leading product candidate, or another one of our product candidates, we may require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise funds when necessary, we may have to reduce or discountinue development, commercialization or clinical testing of some or all of our product candidates or take other cost cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised though the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

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

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

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

- it is uneconomical or the market for the product does not develop or diminishes;

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

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

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

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

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

There may be unforeseen challenges in developing biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal

correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the two animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the two animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

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

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

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

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

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

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

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have

licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

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

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

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

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

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

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

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against

others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

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

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

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

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

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

We have only eight employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Michael Sember, Chief Executive Officer, was hired in December 2004; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was on the Board for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In the fourth quarter of 2004, Alexander P. Haig was appointed Chairman of the Board replacing his father, General (Ret.) Alexander M. Haig, Jr., who resigned from our Board and joined our BioDefense Strategic Advisory Board. Because of this inexperience in operating our business, there continues to be significant uncertainty as to how our management team will perform. We will not be successful if this management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

Our stock price has fluctuated between April 1, 2002 through March 31, 2006, the per share price of our common stock ranged between a high of $1.71 per share to a low of $0.11 per share. As of May 5, 2006 our common stock traded at $0.32. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock has been delisted from the American Stock Exchange

On April 18, 2006 our stock was delisted from the AMEX and we began trading on the Over-the-Counter Bulletin Board (“OTCBB”) under the ticker symbol DORB. We were delisted shortly after March 31, 2006 since we had not increased our shareholder equity above the $6,000,000 required under the maintenance requirement for continued listing.

Because we incurred losses from operations in fiscal 2005, the stockholders’ equity standard applicable to us of the American Stock Exchange’s (AMEX) continued listing requirements is $6,000,000. As of December 31, 2005, we had stockholders’ equity of $1,530,000.

Upon delisting, 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, the price of our common stock may decline and our stockholders may 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 36,600,000 shares of our common stock at a current weighted average exercise price of approximately $0.73;

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

- options to purchase approximately 9,800,000 shares of our common stock of a current weighted average exercise price of approximately $0.61.

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

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

We have secured a $6,000,000 equity financing commitment from Fusion Capital. Under the terms of our April 2006 private placement, we may not access the funds available to us under the Fusion Capital commitment by selling our shares of common stock to Fusion Capital without consent from Iroquois Capital or until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. Our stock price must be above $0.12 in order for Fusion Capital to purchase our shares of common stock. 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 if we are not able to obtain alternative financing.

Holders of our common stock are subject to the risk of additional and substantial dilution to their interests as a result of the issuances of common stock to Fusion Capital.

Shareholders are subject to the risk of substantial dilution to their interests as a result of our issuance of shares to Fusion Capital under the common stock purchase agreement. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock. In addition, in the event we elect to issue more than the 9,962,500 shares previously issued, we will be required to file a new registration statement and have it declared effective by the SEC. If such registration were declared effective by the SEC, Fusion Capital could also sell any shares registered on such a subsequent registration statement and this in turn would result in additional dilution to our other stockholders. If we elect to issue more than the 9,962,500 shares previously issued and the average price at which we sell $6 million of our stock is $0.32 (the closing sale price of our common stock on May 5, 2006) we would issue 18.7 million shares. We do not have the right to sell shares to Fusion Capital at a price below $0.12 per share and accordingly we could not issue more than 50,000,000 shares 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 market price of our common stock. Fusion Capital may sell none, some or all of the registered shares of common stock purchased from us at any time. We expect that the registered shares held by Fusion Capital will be sold over a period of in excess of 13 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of such shares at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might

otherwise wish to effect sales.

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

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

RECENT DEVELOPMENTS

On October 28, 2005, we entered into a binding letter of intent to acquire 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 the letter of intent, which had expired in accordance with its terms on January 15, 2006. The letter of intent provided for a $1 million break-up fee in the event a party notifies the other of its intention not to proceed with the transaction. On January 30, 2006, we were advised by the attorney representing Gastrotech that if we were not willing to comply with the terms of the letter of intent, we would be in material breach of our obligations under the letter of intent and would be obligated to pay Gastrotech a break-up fee of $1 million. Our position is that we do not owe Gastrotech such break-up fee.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over approximately a 15-month period, subject to earlier termination at our discretion. As of May 5, 2006, we sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not sell any additional shares to Fusion Capital without the consent of Iroquois Capital or until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when we resume selling stock to Fusion Capital, in our discretion, we may elect to sell less of our common stock to Fusion Capital than the daily amount, and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. Under the terms of the common stock purchase agreement, we issued to Fusion Capital 450,000 shares of our common stock as a partial commitment fee upon entering into the agreement. Fusion Capital also received an additional 450,000 commitment shares.

On April 10, 2006, we completed the issuance and sale of an aggregate of 13,099,964 shares of our common stock to institutional and other accredited investors for an aggregate purchase price of $3,630,000 pursuant to a securities purchase agreement. 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. Pursuant to a registration rights agreement, we agreed to file this registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

On May 10, 2006, we completed a merger pursuant to which Enteron, the common stock of which we held 89.13% prior to the merger, was merged into a wholly-owned subsidiary of ours. Pursuant to this transaction, we issued issue 3,068,183 shares of our common stock to the Enteron Shareholders in exchange for the all of the outstanding common stock of Enteron that we did not already own.

BUSINESS

Overview

We are a research and development biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of gastrointestinal Graft-versus-Host Disease, "GVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of gastrointestinal GVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs as when resources permit; and (j) acquire or in-license new clinical-stage compounds for development. We were incorporated in 1987. We maintain two active segments; BioTherapeutics and BioDefense.

BioTherapeutics Overview

Through our BioTherapeutics Division, we are in the process of developing oral therapeutic products to treat unmet medical needs. Our therapeutic product, orBec® (oral beclomethasone dipropionate), has completed a randomized, multi-center, double-blinded, placebo-controlled pivotal Phase III clinical trial for the treatment of acute gastrointestinal graft-vs-host disease (GVHD), a form of serious and life-threatening gastrointestinal inflammation associated with allogeneic bone marrow or stem cell transplant therapy. orBec® demonstrated a statistically significant reduction in mortality during the prospectively defined Day 200 post-transplant period and positive trends on it's primary endpoint. While orBec® did not achieve statistical significance in its primary endpoint of time to treatment failure at Day 50 (p-value 0.1177), orBec® did achieve a 70% reduction in mortality compared to placebo (p-value 0.011). orBec® is a highly potent, topically-active glucocorticoid. orBec® has previously been granted Fast Track Designation and received Orphan Drug Designation by the Food and Drug Administration (FDA) for the treatment of gastrointestinal GVHD.

BioDefense Overview

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

September 13, 2004, we were awarded a $5,173,298 grant from the National Institute of Allergy and Infectious Diseases (NIAID) for RiVax™, our genetically engineered vaccine against ricin toxin, one of the most lethal plant toxins known to man. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a new renegotiated F&A rate with the NIH. The grants project period is September 15, 2004 to August 31, 2007 and covers the process development for manufacturing of RiVax™ our recombinant vaccine for ricin toxin. The grant is based on milestones and certain budget amounts are earned as we meet milestones in the development of RiVax™.

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

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

BioTherapeutics Division

orBec®

Our therapeutic product orBec®, is an orally administered corticosteroid that exerts a potent, local anti-inflammatory effect within the mucosal tissue of the gastrointestinal tract. orBec® has recently completed a multicenter, placebo-controlled pivotal Phase III clinical trial in gastrointestinal GVHD. Gastrointestinal GVHD is a life threatening complication of allogeneic bone marrow transplantation for which no FDA-approved therapies exist, making it an area of unmet medical need. The active ingredient in orBec®, beclomethasone 17, 21-dipropionate ("BDP"), is a mucosally active anti-inflammatory agent, with a potent local effect, that is the active ingredient in a variety of currently marketed products including Beconase Aqua (nasal spray for rhinitis), Becloforte (inhalant for asthma), and Propaderm (a topical cream for eczema and psoriasis). There currently is no FDA-approved oral BDP product in the United States. There are a variety of additional gastrointestinal disorders for which a potent, topically-active oral corticosteroid could be beneficial including Irritable Bowel Syndrome, Ulcerative Colitis and Crohn's Disease. We believe that topical steroids such as orBec® delivered to the affected mucosa would suppress the inflammation associated with these disorders while producing fewer adverse side effects than systemic corticosteroids such as prednisone.

orBec® is manufactured as a two-pill formulation (1 mg BDP per pill) administered four times daily (total of 8 mg) for the indication of acute gastrointestinal GVHD. The two-pill combination is comprised of an immediate-release pill designed to primarily dissolve in the stomach and proximal intestine and an enterically-coated pill designed to dissolve in the more alkaline pH portion of the small intestine.

Our goal is to file an NDA with the FDA for orBec® for the treatment of gastrointestinal GVHD in the second quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GVHD to be at between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

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

Pivotal Phase III Clinical Trial

Previous Phase I and Phase II clinical studies demonstrated that a two-pill combination of oral BDP was effective in treating gastrointestinal GVHD, allowing patients to be rapidly tapered off the systemic corticosteroid prednisone, without recurrence of intestinal symptoms (McDonald *et al*., 1998 *Gastroenterology*), and without clinical manifestation of adrenal suppression (Baehr *et al*., 1995 *Transplantation*). Based on this data, we designed a Phase III clinical protocol that was subject to a Special Protocol Assessment (SPA) by the FDA and was similar in design to the previously completed Phase II trial (McDonald *et al.* 1998 *Gastroenterology*). The primary efficacy endpoint of this trial was the time to treatment failure at Study Day 50. Treatment failure was defined as use of prednisone or equivalent IV corticosteroids at doses higher than stated in protocol, or use of any additional other steroid, in response to uncontrolled signs or symptoms of gastrointestinal GVHD. The target enrollment was 130 patients. The pivotal trial was conducted at sixteen bone marrow transplant centers fourteen in the United States and two in France, and the product has been assigned "orphan drug" designation and "fast track" status by the FDA. The trial was a randomized,

double-blind, placebo controlled safety, efficacy and pharmacokinetic trial that was to serve as the basis for a New Drug Application to be filed with the FDA.

In the pivotal Phase III study, orBec® demonstrated a strong positive trend on the primary endpoint of median time to treatment failure at study day 50 and a statistically significant result in the prospectively defined endpoint of median time to treatment failure at study day 80 (p-value 0.0226). The Company believes that the p-value of 0.1177 achieved in the primary endpoint through Day 50 is primarily due to a higher than expected rate of treatment failures during days 0-10 of the study. During such period, patients were receiving high dose prednisone (1-2mg/kg/day) plus either orBec® (8mg/day) or placebo. For purposes of the study, patients that did not begin the rapid taper of high dose prednisone on Day 10 as called for by the regimen were deemed treatment failures for all purposes, including the calculation of statistical significance of time to treatment failure at Day 50. The Company intends to further analyze the Day 0-10 treatment failure group and the statistical impact of this group on the primary endpoint of time to treatment failure at Day 50 and discuss the results of this analysis with the FDA. Encouragingly, the treatment failure rate at Day 50 approached statistical significance (p-value 0.0515). In addition, the secondary endpoint of time to treatment failure at Day 80, as well the treatment failure rate at Day 80, each achieved statistical significance (p-values 0.0226 and 0.0048, respectively).

Perhaps of greatest clinical relevance, orBec® demonstrated a 67% reduction in mortality, registering only 5 (8%) deaths during the prospectively defined Day 200 post-transplant period versus 16 (26%) deaths for the placebo group (p-value 0.011). Based upon separate analysis conducted by the Company, there is also a statistically significant correlation between treatment failure and mortality.

Previous Phase II Study Results

Oral BDP was previously tested in a randomized, double-blind, placebo-controlled Phase II study was conducted at the Fred Hutchinson Cancer Research Center in Seattle (*Gastroenterology*, 1998; 115: 28-35). In that study, 60 patients with gastrointestinal GVHD were randomized to receive conventional prednisone therapy plus either BDP or placebo. Initial responders continued to take BDP or placebo for an additional 20 days, during which time the conventional therapy was rapidly tapered. The primary endpoint for this study was the clinically relevant determination of whether gastrointestinal GVHD patients at Day 30 were or were not able to consume at least 70% of their daily caloric intake by mouth, as compared to intravenous parenteral nutrition administered in the hospital. The treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the BDP and placebo groups respectively, achieving a statistically significant p-value of 0.02. By transplant day-200, three patients (10%) who had been randomized to BDP had died, compared to 6 deaths (21%) among patients who had been randomized to placebo, leading to a 53% reduction in the hazard of day-200 mortality.

New Mortality Findings

At the November, 2005 meeting with the FDA's Oncology Division, the FDA specifically asked for mortality data from the Phase II study as well as long term follow-up mortality data from both studies. In the Phase III pivotal trial, 28 patients (42%) in the placebo group and 18 patients (29%) in the BDP group died within one year of randomization (adjusted hazard ratio 0.54, 95% CI: 0.30, 0.99, p=0.0431, stratified log log-rank test). In the Phase III pivotal trial, a subgroup analysis revealed that among patients who had received stem cells from unrelated donors, the reduction in the risk of day-200 mortality among patients randomized to orBec® was 91%. The new survival analysis of patients enrolled in the earlier Phase II trial suggests that results were similar to those from the pivotal Phase III multi-center study. By one year after randomization, 9 of 29 patients in the placebo group and 6 of 31 patients in the BDP group had died (adjusted hazard ratio 0.55).

In the Phase II trial, there were reductions in the risk of mortality of 55% and 43% at transplant day-200 and one year post-randomized among patients randomized to oral beclomethasone dipropionate, respectively. The comparable survival data from the 129-patient Phase IIII pivotal trial were 66% and 51% reductions in the risk of mortality at

transplant day-200 and one-year post-randomization among patients randomized to orBec®, respectively. In the Phase III pivotal trial, a subgroup analysis revealed that among patients who had received stem cells from unrelated donors, the reduction in the risk of day-200 mortality among patients randomized to orBec® was 94%.

Additionally, in an analysis of the day-200 survival endpoint data from the pivotal Phase III clinical trial, there were no previously undetected imbalances between the treatment and placebo groups that could have favored the orBec® group over the placebo group. In fact, there was a higher proportion of high risk patients in the orBec® group which would be expected to put the orBec® arm at a disadvantage. In spite of this, orBec® was still the factor with the strongest statistical association with survival.

About Graft-versus-Host Disease

Graft-versus-Host Disease occurs in patients following an allogeneic bone marrow transplant in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes in the donor (graft) marrow. Patients with mild to moderate gastrointestinal GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of gastrointestinal GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50 to 70% of the estimated 10,000 annual allogeneic transplant patients in the United States will develop some form of acute gastrointestinal GVHD.

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

Future Potential Indications of orBec®

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

Other Products in BioTherapeutics Pipeline

The following is a brief description of other products in our pipeline. Due to resource limitations, the Company has recently focused its R&D efforts on orBec®, RiVax® and BT-VACC™. When financial circumstances change, the Company may re-initiate development of any or all of these products, all of which are currently available for licensing or acquisition. These products consist of two drug delivery systems that are designed to facilitate the oral delivery of hydrophobic and hydrophilic drugs, including peptides, and an oral form of the immunosuppressant azathioprine. We acquired the formulation of azathioprine (Oraprine™) as a result of the merger of Endorex and CTD in November 2001, also acquired were patent applications licensed from Dr. Joel Epstein of the University of Washington. We conducted a Phase I that established the feasibility of the oral drug to treat oral ulcerative lesions resulting from graft versus host disease. The drug delivery systems, LPM™, LPE™, PLP™, including the use of leuprolide in the LPM™ system, were

developed internally and we have submitted and pursued patents on these products.

Oraprine™

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

LPM™ - Leuprolide

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

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

We were developing two lipid-based systems, LPE™ and PLP™, to support the oral delivery of small molecules of water insoluble drugs. Such drugs include most kinds of cancer chemotherapeutics currently delivered intravenously. The LPE™ system is in the form of an emulsion or an emulsion pre-concentrate incorporating lipids, polymers and co-solvents. 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.

In collaboration with two United States academic research institutions, we are developing vaccine products to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products produced in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits retain the ability to 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.

BioDefense Programs

In collaboration with two United States academic research institutions, we are developing vaccine products to combat the threat posed by two potent biological toxins; ricin toxin and botulinum toxin. Both vaccines under development are recombinant products produced in bacterial hosts and both consist of nontoxic subunits of the native toxins. These subunits retain the ability to 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.

Rivax™ - Ricin Toxin Vaccine

The development of our vaccine against ricin toxin stems from the research (Smallshaw *et al.,* 2002 *Vaccine*) of Dr. Ellen Vitetta at University of Texas Southwestern Medical Center (UTSW). This research has shown that a modified subunit of ricin toxin is non-toxic and highly immunogenic in animals, reproducibly inducing protective immunity in mice challenged with ricin toxin. In collaboration with UTSW, we have manufactured the vaccine in small batches in their current good manufacturing practices ("cGMP") facility, developed a stable formulation, filed an IND and initiated a pilot Phase I safety and immunogenicity trial. We have completed the pilot trial which was a dose escalation clinical trial. This trial marks the first time a ricin toxin vaccine has ever been clinically tested in humans. The trial enrolled 15 volunteers in groups of 5 who were vaccinated with three successive monthly injections of the same dose level of RiVax™. Three dose levels of RiVax™ were evaluated. The vaccine was prepared without an adjuvant to determine whether the subunit itself was immunogenic and safe. Even without an adjuvant, RiVax™ induced antibodies in all five of the individuals who received the highest dose, four out of five who received the intermediate dose, and one out of five who received the lowest dose levels. The vaccine was well tolerated in all individuals with only mild side effects that are typical of reactions to vaccines injected intramuscularly. These side effects included mild transient headaches and sore arms. Despite the absence of an adjuvant, antibodies were present in the blood of several volunteers for as long as 127 days after their last vaccination. The functional activity of the antibodies was confirmed by transferring serum globulins from the vaccinated individuals along with active ricin toxin to sensitive mice, which then survived subsequent exposure to ricin toxin. The results of this study were published in the *Proceedings of the National Academy of Sciences*. Based on these results, we are planning additional human clinical trials with an adjuvant formulation of the vaccine, which is now being evaluated in stability and toxicology trials.

We have developed a robust process for manufacturing the vaccine at scale with Cambrex under the auspices of a $6,433,316 NIH challenge grant awarded to foster development and manufacturing. We have extensively characterized the different stages in the process and have performed the process under cGMP in anticipation of Phase II trials with the vaccine. We have also developed a formulation of the vaccine using salts of aluminum as an adjuvant to prolong and enhance the protective immune response in humans. In conjunction with Phase II trials, we are planning to conduct pivotal animal trials of the vaccine to elaborate on the FDA "two animal" rule, which permits licensure of vaccines based on the results of safety tests in humans and efficacy results in animals in situations where the evaluation in humans is ethically not permitted. The goal of these studies is to determine the level of antibodies in humans that is correlated to protection against exposure in animals. This must be done to be able to choose the correct dose and dosing regimen for humans. In the case of ricin, it is not ethical to expose humans to ricin post vaccination, so "correlates of immunity" must be established in animal models. Our goal is to make a ricin vaccine available for the United States government's Strategic National Stockpile. We have an exclusive license agreement with UTSW for its ricin vaccine technology.

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 Centers for Disease Control and Prevention (CDC) have classified ricin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

BT-VACC™ - Botulinum Toxin Vaccine

Botulinum toxin is the product of the bacteria *Clostridium botulinum*. Botulinum toxin is one of the most poisonous natural substances known to mankind. 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.

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania (Park and Simpson 2003 *Infection and Immunity*). There are seven different serotypes of botulinum toxin and no cross immunogenicity exists between these serotypes. Any vaccine will therefore require multiple antigens to protect against the different serotypes. The antigen consists of a segment of the heavy chain of botulinum toxin that is non-toxic and immunogenic. After oral or intranasal immunization, the antigen elicits antibodies that protect vaccinated animals against massive lethal doses of native toxin. Ability for a subunit protein to induce antibodies after oral or nasal immunization is atypical for protein subunit vaccines. The reason that a mucosal vaccine is possible for botulinum toxin stems from the fact that the heavy chain of the toxin binds avidly to epithelial cells and is transported to lymphoid tissue in the gastrointestinal and respiratory tract. The majority of the protective epitopes are located on the heavy chain, which does not contain enzymatic activity and is devoid of toxicity. We are currently developing formulations containing antigens of three serotypes and are testing those as oral or nasal vaccines. To this point, we have demonstrated that it is possible to combine three antigens in a multivalent formulation and administer them by the respiratory route and induce protection against each corresponding toxin. Our prototype vaccine consists of antigens of type A, B, and E, which are the most prevalent serotypes in natural human infections and are thought to be the ones most likely to be used as bio-weapons. Our immediate plans are to obtain antigen from a single serotype (through manufacture or collaboration), conduct the necessary preclinical toxicology tests for an IND, and test an oral formulation for safety and immunogenicity in human volunteers. Our goal is to produce a multivalent vaccine and make it available for the U.S. government's Strategic National Stockpile. We have an exclusive license agreement with Thomas Jefferson University for the oral and intranasal use of their botulinum toxin vaccine technology.

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

products on an emergency basis. Further, there are additional legislation in front of Congress, such as BioShield II, that will address additional issues such as patent extension and liability that may be of benefit to the Company in this business.

Summary of Our Products in Development

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

Biodefense Products

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

BioTherapeutic Products

Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of Intestinal Graft-versus-Host Disease	Pivotal Phase III Clinical Trial Completed, NDA to be filed
Oraprine™	Oral lesions resulting from Graft-versus-Host Disease	Phase I Complete
LPM™ - Leuprolide	Endometriosis and Prostate Cancer	Pre-Clinical
LPE™ and PLP™ Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

The Drug Approval Process

General

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

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

processes, manufacturing and marketing practices established by the FDA must be satisfied.

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

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

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

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

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

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young

and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the two animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and the Company may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the two animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

Marketing Strategies

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

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

Competition

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

Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Avant Immunotherapeutics, Inc., Bioport Corporation, VaxGen, Inc., Chimerix, Inc., Biosante, Inc., ID Biomedical Corporation, Human Genome Sciences, Inc., CpG Immunotherapeutics, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., and others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. VaxGen and Avecia Biotechnology, Inc. have both received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen has also recently received approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of Anthrax vaccine. CpG Immunotherapeutics, Inc. has received a $6 million Department of Defense grant to develop vaccine enhancement technology. ID Biomedical Corporation, has entered into an $8 million contract to develop a plague vaccine. We have not yet been awarded any such contract funding. Additionally, we face competition from other companies which have existing governmental relationships, such as Dynport Vaccine Company, LLC, a prime contractor to the U.S. Department of Defense. Dynport currently has a $300 million contract to develop vaccines for the U.S. Military, including anthrax, and botulinum toxin vaccines.

orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat graft-vs.-host disease 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.

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

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

We are not aware of any marketed products or products in active development to selectively treat gastrointestinal GVHD. We also 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.

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 10 years exclusivity in Europe for the

use of orBec® in the treatment of gastrointestinal 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 gastrointestinal 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.

orBec® License Agreement

In October 1998, our 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 for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine for initial license fees of $200,000 of our common stock and $100,000 in cash. Subsequently, in October of 2004, we negotiated the remaining oral rights to the ricin vaccine for additional license fees of $150,000 in cash. Our license obligates us to pay $50,000 in annual license fees.

On March 1, 2005 we signed a sponsored research agreement with UTSW extending through March 31, 2007. The cost of this research is approximately $190,000. The research will grant us certain rights to such intellectual property.

Botulinum Toxin Vaccine Intellectual Property

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

Microvax™ Intellectual Property

During 1998, our former joint venture with Élan Pharmaceuticals, Inc., Innovaccines Corporation, acquired from the Southern Research Institute/University of Alabama broadly issued U.S. and international patents relating to the oral administration of vaccines. Microspheres of these dimensions are preferentially absorbed by lymphoid tissues in the gastrointestinal tract and other mucosal lymphoid tissue, resulting in higher efficacy for orally and mucosally applied vaccines. In 2002, we acquired Élan's interest in Innovaccines. We subsequently amended our existing agreement with the Southern Research Institute (Brookwood Pharmaceuticals)/University of Alabama for rights to use their patents and technologies for commercialization of microencapsulated vaccines that permit oral delivery of antigenic compounds (vaccines). In April 2003, after the inception of our biodefense program, the license agreement was amended to provide us with the rights to nasal delivery of anthrax and ricin antigens. In keeping with our current focus, the Southern Research Institute/University of Alabama license agreement has again been amended to allow us to keep the nasal rights for the ricin vaccine while returning all other rights. This most recent amendment requires us to pay a yearly license fee in the amount of $60,000 and monthly patent maintenance of $5,000.

Employees

As of December 31, 2005, we had eight full-time employees, two of whom are Ph.D.s.

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

Research and Development Spending

We spent approximately $3,700,000 in 2005 and 2004 on research and development.

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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

Business Overview and Strategy

We are a research and development biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of gastrointestinal Graft-versus-Host Disease, "GVHD" as well as to prepare submission of a Marketing Authorization Application ("MAA") with the European Central Authority, European Medicine Agency ("EMEA"); (b) consider prophylactic use studies of orBec® for the prevention of gastrointestinal GVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; (i) reinitiate development of our other biotherapeutics products namely Oraprine™, LPM™-Leuprolide, and LPE™ and PLP™ Systems for Delivery of Water-Insoluble Drugs as resources permit; and (j) acquire or in-license new clinical-stage compounds for development. We were incorporated in 1987. We maintain two active segments; BioTherapeutics and BioDefense.

orBec®

Our goal is to file an NDA with the FDA for orBec® for the treatment of gastrointestinal GVHD in the second quarter of 2006. We have assembled an experienced team of employees and contractors who are currently working on all aspects of the NDA preparation, including data management, data analysis, and biostatistics medical writing. Manufacturing of the requisite batches of drug product (registration batches) is completed and these batches are currently undergoing stability testing.

We anticipate the market potential for orBec® for the treatment of gastrointestinal GVHD to be between 50 and 70 percent of the approximately 10,000 bone marrow and stem cell transplants that occur each year in the U.S.

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

RiVax™

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

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal 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. Our preclinical data to date, demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E and multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals. Further, we are engaged in formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™ a high yield expression system based on *Pseudomonas fluorescens.* Up to this point we have successfully demonstrated successful high expression of soluble material from all three Hc50 vaccine candidates.

Oraprine™

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

LPM™ - Leuprolide

LPM™ - Leuprolide is an oral dosage formulation of the peptide drug leuprolide, a hormone-based drug that is among the leading drugs used to treat endometriosis and prostate cancer, which utilizes a novel drug delivery system composed of safe and well characterized ingredients to enhance intestinal absorption. The LPM™ system incorporates biocompatible lipids and polymers and is potentially useful for a wide variety of molecular structures of

water-soluble drugs, particularly those based on peptides. Although both small molecules and large molecules can be incorporated into our system, there is a molecular size cutoff for a commercially viable oral bioavailability enhancement, and this system is most effective with hydrophilic drugs/peptides below 5,000 Daltons in molecular weight. Utilizing a simple and scaleable manufacturing process, aqueous solutions of peptides can be incorporated into lipid-polymer mixtures forming stable micelles.

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

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

Critical Accounting Policies

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

Intangible Assets

Currently, the most significant estimate or judgment that we make is whether to capitalize or expense patent and license costs. License costs are expensed unless the license fee is for more than one year. 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 at least annually or 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.

Research and Development Costs

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

Revenue Recognition

We recognize revenue from government grants. These revenues are recorded in the period in which they are earned. The consideration we receive is based upon a cost plus Facilities and Administrative (F&A) rate that provides funding for overhead expenses.

Material Changes in Results of Operations

We are a research and development company. The 2005 revenues and associated expenses were from an NIH Grant which we received in September 2004, and from an FDA grant which we received in September 2005. The NIH grant was associated with our ricin vaccine. The original amount of the NIH grant was $5,173,298. This was increased on May 6, 2005, to $6,433,316. The increase of $1,260,018 was awarded based on a new renegotiated F&A (facilities and administrative) rate with the NIH. Part of this increase was attributed to the NIH reimbursement for overhead expenses for 2004 in the amount of $285,891 in the second quarter of 2005. This new rate provided a fixed rate for facilities and administrative costs (overhead expenditures) that is applied against all costs associated with the grant awarded. The FDA grant was awarded on September 23, 2005 for the “Oral BDP for the Treatment of GI GVHD.” We begin recognizing revenue for this grant in the fourth quarter of 2005. The total amount of the one-year grant is $318,750.

For the year ended December 31, 2005, we had grant revenues of $3,075,736 as compared to $997,482 in the 12 months ended December 31, 2004, an increase of $2,078,254, or 208%. We also incurred expenses related to that revenue in 2005 and 2004 of $2,067,034 and $936,636, respectively, an increase of $1,130,398, or 121%. These costs relate to payments made to subcontractors and universities in connection with the grants.

Although we have a gross profit, the gross profit is a result of the increase in the NIH award for a higher and more comprehensive F&A rate to provide for overhead expenditures and the FDA grant. In addition, the gross profit of $1,008,702, for the twelve months ended December 31, 2005, respectively, includes $285,891 from 2004, as reimbursement in the second quarter of 2005 for the new F&A rate.

For the 12 months ended December 31, 2005, we had a net loss applicable to common stockholders of $4,720,260 as compared to a $6,374,769 net loss applicable to common stockholders for the 12 months ended December 31, 2004, a decrease of $1,654,509, or 26%. Net loss applicable to common stockholders included the impact of preferred stock dividends, which totaled $503,195 in 2004, as compared to $0 in 2005. This decrease in the net loss is due largely to our increased gross profit generated by the government grants and to the costs reductions in general and administrative expenses.

During 2005, our research and development spending increased to $3,681,137 as compared to $3,656,776 for 2004; an increase of $24,361 or 1% as compared to 2004. In 2005 we had higher expenses in the third and fourth quarters for regulatory and filing consultant costs associated with the preparation of the NDA filing for orBec®.

General and administrative expenses for the 12 months ended December 31, 2005 were $2,162,616 as compared to $2,321,186 for the 12 months ended December 31, 2004, a decrease of $158,570, or 7%. In 2004 we had severance

payments and accrued severance due former employees approximating $160,000. For 2005, the decrease was primarily attributed to a reversal of $284,855 from reported income in 2004 for the variable accounting treatment of options granted to new employees under the stock option plan that exceeded the number of allowed stock options under the plan.

We are required to perform an annual impairment test on intangible assets, which we perform in the fourth quarter of each year. During the fourth quarter of 2005, we determined that our intangible assets, namely, our patents were impaired by $164,336. The net book value of the intangible assets will be reviewed annually and when impairment is indicated the resulting expense will be taken.

Interest income for the 12 months ended December 31, 2005 was $78,242 as compared to $66,539 for the 12 months ended December 31, 2004, an increase of $11,704 or 18%. This was primarily due to an increase in the number of days of available interest bearing cash balances in 2005 as compared to 2004 and higher interest rates on those balances.

Interest expense for the 12 months ended December 31, 2005 was a $36,549 credit as compared to $20,977 expense for the 12 months ended December 31, 2004, an increase of $57,546 or 274%. This was due to reversal of interest expense resulting from an agreement reached with a pharmaceutical company for settlement of a note payable. This agreement required a payment of $41,865 in lieu of the $83,729 of accrued interest.

Financial Condition

As of December 31, 2005, we had cash and cash equivalents of $821,702 as compared to $2,332,190 as of December 31, 2004 and negative working capital of $319,675 as compared to $1,055,922 as of December 31, 2004. For the 12 months ended December 31, 2005, our cash used in operating activities was approximately $4,700,000, versus approximately $4,400,000 in 2004.

In 2004, we granted options to employees and directors that were conditional upon stockholder approval of an amendment to our 1995 omnibus option plan. Therefore, a measurement date did not exist until approval could be gained at our annual stockholder meeting. In December 2004, we recorded a noncash expense of $284,555.

We expect our expenditures for 2006, under existing product development agreements and license agreements pursuant to letters of intent and option agreements to approximate $3,600,000. We anticipate grant revenues to offset manufacturing and research expenditures for the development of our ricin vaccine and for orBec® in the amount of approximately $2,300,000, pending completion of certain milestones.

As of September 30, 2005, we paid a note due of $115,948, which represents the remaining amount payable to a pharmaceutical company in connection with our joint ventures.

The following summarizes our contractual obligations at December 31, 2005, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligations	Year 2006	Year 2007
Non-cancelable obligations (1)	$ 52,628	$ -
TOTALS	**$ 52,628**	**$ -**

(1) 3 year lease on corporate office entered into in 2003 and expiring in 2006.

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. Fusion has agreed to purchase on each trading day $20,000 of our common stock up to an aggregate of $6,000,000 million over approximately a 15-month period, subject to earlier termination at our discretion. We have sold 329,540 shares of common stock to Fusion Capital. Pursuant to the terms of our April 2006 private placement, we may not access the funds available under the Fusion Capital commitment by selling our shares of common stock to Fusion Capital without the prior consent of Iroquois Capital until the earlier to occur of (i) seven business days after an FDA advisory panel meeting regarding the New Drug Application for orBec® or (ii) the date the FDA responds to the New Drug Application for orBec®. If and when we resume selling stock to Fusion Capital, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. We will sell our shares of common stock to Fusion Capital based upon the future market price of the common stock without any fixed discount. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12. We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases.

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. Such 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.

On April 10, 2006, we completed the sale of an aggregate of 13,099,964 shares of our common stock to institutional and other accredited investors for an aggregate 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. Pursuant to a registration rights agreement, we agreed to file this registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

Based on our current rate of cash outflows, and provided we have access to the Fusion continuous secondary facility, we believe that our cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through the second quarter of 2007. If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms or at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the fiscal year ended December 31, 2004.

DIRECTORS AND EXECUTIVE OFFICERS

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

Name	Age	Position
Alexander P. Haig, J.D.	53	Chairman of the Board
Steve H. Kanzer, C.P.A., J.D.	42	Vice Chairman
Michael T. Sember, M.B.A.	56	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	41	Chief Financial Officer, and Director
James S. Kuo, M.D., M.B.A.	41	Director
T. Jerome Madison, C.P.A.	65	Director
James Clavijo, C.P.A., M.A.	40	Controller, Treasurer, and Corporate Secretary

Alexander P. Haig, J.D., has been a director since 2004 and currently serves as our non-employee Chairman of the Board. Since 1988, Mr. Haig has served as the managing director of Worldwide Associates, Inc., a firm representing multi-national corporations and early stage development companies in marketing and business strategies. From 1992 to 1996, Mr. Haig also served as president of US-CIS Ventures, a privately held company active in transactions and projects in China and the former Soviet Union. From 1999 to 2002, Mr. Haig also served as Chairman and CEO of Sky Station International, Inc., a privately held telecommunications company. Mr. Haig has worked on a wide variety of projects for Worldwide Associates with particular emphasis on aerospace and pharmaceutical technologies and was active in providing strategic and financial advice to a broad range of companies from early stage through initial public offerings, including America Online, Inc. Previously a partner in a large private law firm, Mr. Haig concentrated on international trade and corporate matters. He received his undergraduate and law degrees from Georgetown University.

Steve H. Kanzer, C.P.A., J.D., has been a director since 1996 and currently serves as the non-executive Vice Chairman of the Board. Mr. Kanzer served as our Interim President from June 30, 2002 through January 4, 2003. Since December 2000, he has served as Chairman of Accredited Ventures Inc. and Accredited Equities Inc., respectively, a venture capital firm and NASD member investment bank specializing in the biotechnology industry. He also serves as President and/or a member of the board of directors of several private biopharmaceutical companies, including Pipex Therapeutics, Solovax, Inc., General Fiber, Inc., Effective Pharmaceuticals, Inc. and CD4 Biosciences, Inc.., each of which are involved in the licensing and development of clinical stage investigational new drugs and life science technologies. Since September 2004, he assumed the role as Chairman and Chief Executive Officer of Pipex Therapeutics, Inc., a biopharmaceutical company located in Ann Arbor, Michigan focusing on late stage products. From January 2001 until October 2003, Mr. Kanzer also served as President of Developmental Therapeutics, Inc. until its acquisition by Titan Pharmaceuticals, Inc. in October 2003. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer was a co-founder of Paramount Capital, Inc. in 1992 and served as Senior Managing Director - Head of Venture Capital of Paramount Capital until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies, including our company as well as a private biopharmaceutical company, Corporate Technology Development, Inc. ("CTD"). Mr. Kanzer was full-time Chief Executive Officer of CTD from March 1998 until December 2000 and part-time Chief Executive Officer from December 2000 until our company completed its acquisition of CTD in November 2001. From 1995 until June 1999, Mr. Kanzer was a founder and Chairman of Discovery Laboratories, Inc., a public biotechnology company. From 1997 until 2000, he was President of PolaRx Biopharmaceuticals, Inc. a biopharmaceutical company that licensed and developed TRISENOX®, a leukemia drug currently marketed by Cephalon, Inc. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York. Mr. Kanzer received his J.D. from New York

University School of Law and a B.B.A. in accounting from Baruch College.

Michael T. Sember, M.B.A., became the Company's Chief Executive Officer, President and Director in December 2004. Mr. Sember brings 30 years of broad experience working with both public and private pharmaceutical and biotech companies in the U.S. and Europe. Mr. Sember has an extensive business development, operating and financial background which includes involvement with nearly 100 licensing transactions and several corporate acquisitions. Formerly he was Managing Director of EGB Advisors, LLC from December 2003 to December 2004, a business consulting firm and biotech incubator. Prior to joining EGB Advisors, LLC he was President and Chief Operating Officer of Women First Healthcare, from September 2003 to December 2003, a specialty pharmaceutical company. Prior to joining Women First Healthcare, he was President and Chief Operating Officer of Deltagen, Inc., from April 2002 to December 2002, a genomics company. Both Women's First Healthcare and Deltagen filed bankruptcy petitions subsequent to Mr. Sember's tenure at each company. Mr. Sember was not a member of the executive management or an employee of either company during the period leading up to their engagement of him to assist in their efforts to accomplish a restructuring of their business. Prior to joining Deltagen, Inc. he was Executive Vice President of Business Development with Élan Corporation, from September 1991 to March 2002. At Élan he was responsible for building a strategic alliance portfolio, which included over 30 products in clinical development across several therapeutic areas including neurology, oncology, and pain management. During this period he generated approximately $900 million in licensing revenue during the development of the alliance portfolio. While at Élan he was also responsible for managing an investment portfolio valued at approximately $1.25 billion. In addition to this experience Mr. Sember has served on the Boards of eight public and private biotech companies and on the Advisory Boards of several venture capital firms, and currently serves on the board of Directors of Iomed Inc., a publicly traded company. Mr. Sember received a bachelor's degree from the University of Pittsburgh and a Master of Business Administration degree from Rockhurst University.

Evan Myrianthopoulos, has been a director since 2002 and is currently the Chief Financial Officer after joining the Company 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., a public specialty pharmaceutical company developing respiratory therapies. During his tenure at Discovery from June 1996 to November 2001, Mr. Myrianthopoulos held the positions of Chief Financial Officer and Vice President of Finance, where he was responsible for raising approximately $55 million in four private placements. He also helped negotiate and managed Discovery's mergers with Ansan Pharmaceuticals and Acute Therapeutics. Prior to co-founding Discovery, Mr. Myrianthopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm. Prior to joining Paramount Capital, 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 S. Kuo, M.D., M.B.A., has been a director since 2004. Since January 2003, Dr. Kuo was a founder, and currently serves as Chairman and Chief Executive Officer of BioMicro Systems, a private nanotechnology company. Formerly, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories, Inc. from January 2002 to December 2002, where he raised over $22 million in initial private funding and successfully took the company public. Prior to that, he served as Vice President Business Development, from 2001 to 2002, of Metabasis, Inc. From 2000 to 2001, Dr. Kuo served as Vice President Worldwide Business Development of Genset Corporation. He has held senior business development positions at Pfizer, and Myriad Genetics. Dr. Kuo has also been Managing Director of Venture Analysis at HealthCare Ventures and Vice President at Paramount Capital Investments. Dr. Kuo is also a founder and former director of ArgiNOx, a private cardiovascular drug development company. Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

T. Jerome Madison, C.P.A., M.B.A., has been a director since May 2005 and is currently a General Partner at Founders Court, a company specializing in management buyouts of companies with significant growth potential. From 1982 to 1986, he was a co-founder and Chief Financial Officer of Cytogen, a cancer biotechnology company. From 1977 to 1982, he was with Rhone Poulenc Rorer (n/k/a Sanofi-Aventis), a major international pharmaceutical company, where he held the position of Corporate Controller and Chief Accounting Officer. Prior to that, Mr. Madison held financial positions at Abbott Laboratories and KPMG. Prior to joining KPMG, Mr. Madison served in the U.S. Navy as a Naval Flight Officer. Mr. Madison is a Certified Public Accountant and received his B.S. from Wharton School of the University of Pennsylvania and his M.B.A. from Monmouth University.

James Clavijo, C.P.A., M.A. Mr. Clavijo joined our company in October 2004 and is currently our Controller, Treasurer, and Corporate Secretary. He brings 15 years of senior financial management experience, involving both domestic and international entities, and participating in over $100 Million in equity and debt financing. Prior to joining DOR, Mr. Clavijo, held the position of Chief Financial Officer for Cigarette Racing Team (Miami, FL), from July 2003 to October 2004. During his time with Cigarette he was instrumental in developing a cost accounting manufacturing tracking system and managed the administration and development of an IRB Bond related to a 10 acre, 100,000 square foot facility purchase. Prior to joining Cigarette Racing Team, Mr. Clavijo held the position of Chief Financial Officer for Gallery Industries, from November 2001 to July 2003, a retail and manufacturing garment company. Prior to joining, Gallery, he served as Corporate Controller, for A Novo Broadband, from December 2000 to November 2001, a repair and manufacturing telecommunications company where he managed several mergers and acquisitions and corporate restructuring. Prior to joining A Novo Broadband, he served as Chief Financial Officer of AW Industries, from August 1997 to December 2000, a computer parts manufacturer. He also, held the position of Finance Manager for Wackenhut Corporation in the U.S. Governmental Services Division. In addition, he served in the U.S. Army from 1983 to 1996 in both a reserve and active duty capacity for personnel and medical units. Mr. Clavijo holds a Master in Accounting degree from Florida International University, a Bachelor in Accounting degree from the University of Nebraska, and a Bachelor in Chemistry degree from the University of Florida. Mr. Clavijo is a licensed Certified Public Accountant in the state of Florida.

General Alexander M. Haig, Jr., Mr. Haig currently serves on our Strategic Advisory Board. He previously served as Chairman of the Board of Directors from December 2002 to November 2004. Since 1984, Mr. Haig has been Chairman and President of Worldwide Associates, Inc., a Washington D.C. based international advisory firm. He served as Secretary of State (1981-82), President and Chief Operating officer of United Technologies Corporation (1979-81), and Supreme Allied Commander in Europe (1974-79). Previously, he was White House Chief of Staff for the Nixon and Ford administrations, Vice Chief of Staff of the U.S. Army and Deputy National Security Advisor. Mr. Haig currently serves on the Board of Directors of MGM Mirage, Inc. and Metro-Goldwyn Mayer, Inc. He is also the host of his own weekly television program, "World Business Review".

EXECUTIVE COMPENSATION

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2003, 2004 and 2005, to the persons who served as our Chief Executive Officers, and each of the two other most highly compensated executive officers during 2005 (collectively, the "Named Executive Officers").

Name	Position	Years	Annual Salary	Annual Bonus	All Other Compensation	Long term Compensation Awards Securities Underlying Options
		2005	$300,000	$100,000	$57,398	2,000,000

Michael Sember (1)	CEO & President	2004	$20,000	-	-	2,000,000
Evan Myrianthopoulos (2)	CFO	2005	$185,000	$50,000	$35,744	-
		2004	$25,694	-	-	650,000
James Clavijo (3)	Controller, Treasurer & Secretary	2005	$125,000	$25,000	-	150,000
		2004	$27,500	-	-	100,000

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(1) Mr. Sember joined in December 2004. Mr. Sember deferred payment of half of his 2005 annual bonus or $50,000 into 2006. Other Compensation includes costs for transportation, travel and lodging.

(2) Mr. Myrianthopoulos joined in November 2004 as President and Acting Chief Executive Officer and then in December 2004 he accepted the position of Chief Financial Officer. Mr. Myrianthopoulos deferred payment of half of his 2005 annual bonus or $25,000 into 2006. Other Compensation includes costs for transportation, travel and lodging.

(3) Mr. Clavijo joined in October 2004.

The following table contains information concerning options granted to the Named Executive Officers during the fiscal year ended December 31, 2005. We have never issued Stock Appreciation Rights.

Named Executive Officer	Number of Securities Underlying Options Granted	Percentage of Total Options Granted to Employees in Fiscal Year (1)	Exercise Price ($/share)(2)	Expiration Date
Michael Sember	-	N/A	N/A	N/A
Evan Myrianthopoulos	-	N/A	N/A	N/A
James Clavijo (3)	150,000	30%	$0.45	2/22/2015

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(1) Based on options to purchase an aggregate of 500,000 shares of our common stock granted to employees and non-employee board members in the fiscal year ended December 31, 2005, including all options granted to the Named Executive Officers in all capacities in the fiscal year ended December 31, 2005.

(2) The exercise price of each grant is equal to the fair market value of the company's common stock on the date of the grant.

(3) Mr. Clavijo's options vested 50,000 on date of grant, February 22, 2005, with the balance vesting every three months from grant date, at a rate of 8,333 options per three month period.

Fiscal Year-End Option Table

The following table provides information on the total number of exercisable and unexercisable stock options held at December 31, 2005 by the Named Executive Officers. None of the Named Executive Officers exercised any options during fiscal year 2005.

Fiscal Year-End Option Values

	Number of Securities Underlying Unexercised Options at Fiscal Year-End		Value of Unexercised In-the-Money Options at Fiscal Year-End	
Named Executive Officer	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable(1)**
Michael Sember	1,120,000	880,000	-	-
Evan Myrianthopoulos	316,668	333,332	-	-
James Clavijo	108,332	141,668	-	-

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(1) Based on the difference between the option's exercise price and a closing price of $0.27 for the underlying common stock on December 31, 2005 as reported by the American Stock Exchange.

Employment and Severance Agreements

During February 2005, we entered into a three year employment agreement with James Clavijo. Pursuant to this employment agreement we agreed to pay Mr. Clavijo a base salary of $125,000 per year. After one year of service Mr. Clavijo would be entitled to a minimum annual bonus of $25,000. We agreed to issue him options to purchase 150,000 shares of our common stock, with one third immediately vesting and the remainder 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. 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.

During December 2004, we entered into a three year employment agreement with Evan 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. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Myrianthopoulos six months severance subject to setoff, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. Mr. Myrianthopoulos also received 150,000 options, vested immediately when he was hired in November 2004, as President and Acting Chief Executive Officer.

During December 2004, we entered into a three year employment agreement with Michael T. Sember, M.B.A. Pursuant to this employment agreement we agreed to pay Mr. Sember a base salary of $300,000 per year. After one year of service Mr. Sember would be entitled to a minimum annual bonus of $100,000. We agreed to issue him options to purchase 2,000,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "just cause" as defined by this agreement, we would pay Mr. Sember six months severance, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date.

During July 2003, we entered into a three year employment agreement with Geoff Green. Pursuant to this employment agreement we agreed to pay Mr. Green a base salary of $100,000 per year. After one year of service he would be entitled to an annual bonus of $20,000. We agreed to issue him options to purchase 300,000 shares of our common stock, with one third immediately vesting and the remainder vesting over two years. Upon termination without "just

cause" as defined by this agreement, we would pay Mr. Green three months severance, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. In November 2003, Mr. Green also received options to purchase 400,000 shares of our common stock, with vesting based on milestones. In July 2004, Mr. Green accepted the position of President and Acting Chief Executive Officer and received an increase in salary to $145,000. On November 9, 2004, Mr. Green resigned.

During March 2003, we entered into a three year employment agreement with Ralph M. Ellison M.D., M.B.A. Pursuant to this employment agreement we agreed to pay Dr. Ellison a base salary of $200,000 per year. Upon the completion of the equity financing, Dr. Ellison received an increase in base salary to $300,000 per year, as well as a bonus on his anniversary of 30% of his yearly salary. We agreed to issue him options to purchase 2,000,000 shares of our common stock, with one third immediately vesting and the remainder vesting over two years. Upon termination without "just cause" as defined by this agreement, we would pay Dr. Ellison six months severance, as well as any unpaid bonuses and all of his options would immediately become vested in full. On July 9, 2004, Dr. Ellison resigned from the Company and entered into a separation agreement and general release in which we agreed to pay Dr. Ellison six months' severance and provide him with the right to exercise his 2,000,000 vested options received pursuant to his employment agreement for a period of one year from his resignation date.

Director Compensation

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

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

On November 10, 2004, we entered into a letter agreement with Alexander P. Haig, to serve as the Chairman of the Board of Directors. We agreed to issue to him options to purchase 1,000,000 shares of our common stock, with 500,000 vesting immediately and 500,000 vesting in one year. In addition, on November 10, 2004, we entered into a one year consulting agreement with Worldwide Associates, Inc., for a fee of $16,500 per month. Mr. Haig is the managing director of Worldwide Associates, Inc. and General Haig is its President.

On December 23, 2002, we entered into a letter agreement with General Alexander M. Haig, Jr. to serve as the Chairman of the Board of Directors. We agreed to pay General Haig a retainer of $50,000 per year, and issued to him options to purchase 2,000,000 shares of our common stock. On November 10, 2004, the retainer portion of this agreement was terminated and General Haig was given three years in which to exercise his options.

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the Common Stock as of May 5, 2006, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them. Except as otherwise indicated, each stockholder's percentage ownership of our common stock in the following table is based on 65,395,814 shares of common stock outstanding as of May 5, 2006.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Silverback Asset Management, LLC (1)	3,837,700	5.72 %
SF Capital Partners (2)	3,817,046	5.61 %
Alexander P. Haig (3)	1,050,000	1.58 %
Steve H. Kanzer (4)	2,135,635	3.21 %
James S. Kuo (5)	155,000	*
T. Jerome Madison (6)	100,000	*
Evan Myrianthopoulos (7)	794,667	1.15 %
Michael T. Sember (8)	1,865,440	2.78 %
James Clavijo (9)	116,665	*
All directors and executive officers as a group (7 persons)	5,581,977	9.01 %

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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 May 5, 2006, 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 65,395,814 shares of common stock outstanding as of May 5, 2006.

(1) Includes 1,665,000 shares of common stock issuable upon exercise of warrants until August 2010. Reference to this was as reported on Schedule 13G filed with the SEC on February 14, 2006. According to this Schedule 13G, Elliot Bossen may be deemed to be a beneficial owner of all of these shares as a result of acting as the sole managing member of Silverback, and Silverback Master Ltd. may be deemed the beneficial owner of 3,108,000 of these shares. The address for Silverback is 1414 Raleigh Road, Suite 250, Chapel Hill, NC 27517.

(2) Includes 1,139,387 shares of common stock beneficially owned by SF Capital Partners Ltd, 1,012,659 shares of common stock issuable upon exercise of warrants within 60 days and 1,665,000 shares of common stock issuable upon exercise of warrants until August 2010. Reference to this was as reported on Schedule 13G filed with the SEC on February 15, 2005. According to this Schedule 13G, Michael A. Roth and Brian J. Stark may be deemed to be beneficial owners of these shares as a result of their acting as managing members of Stark Offshore Management, LLC, which acts as investment manager and has sole power to direct the management of SF Capital. The address for SF Capital Partners Ltd. is 3600 South Lake Drive St. Francis, WI 53235.

(3) Consists of 1,050,000 options to purchase common stock within 60 days of May 5, 2006. The address of Mr. Haig is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(4) Includes 1,069,437 shares of common stock owned by Mr. Kanzer, 349,398 warrants to purchase shares of common stock and 716,800 options to purchase common stock within 60 days of May 5, 2006. The address of Mr. Kanzer is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(5) Includes 150,000 options to purchase common stock and 5,000 warrants to purchase shares of common stock within 60 days of May 5, 2006. The address of Dr. Kuo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(6) Includes 100,000 options to purchase common stock within 60 days of May 5, 2006. The address of Mr. Madison is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(7) Includes 608,335 options to purchase common stock and 186,342 warrants to purchase common stock within 60 days of May 5, 2006. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(8) Includes 1,685,000 options to purchase common stock within 60 days of May 5, 2006. The address of Mr. Sember is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

(9) Includes 116,665 options to purchase common stock within 60 days of May 5, 2006. The address of Mr. Clavijo is c/o DOR BioPharma, 1691 Michigan Ave, Suite 435, Miami Beach, FL 33139.

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.

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)	9,826,838	$ 0.61	6,800,000
Equity compensation plans not approved by security holders	-	-	-
TOTAL	9,826,838	$0.61	6,800,000

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(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Out Plan expired in 2005 and thus no securities remain available for future issuance under that plan.

SELLING STOCKHOLDERS

The following table presents information regarding the Selling Stockholders. Neither the Selling Stockholder nor any of their affiliates have held a position or office, or had any other material relationship, with us.

Name of Selling Stockholder	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
Iroquois Master Fund LTD(2)	5,052,328	7.44	5,052,328	-	*
Platinum Partners Long Term Growth III(3)	4,330,566	6.41	4,330,566	-	*
Alpha Capital AG/CO LH Financial(4)	3,608,806	5.37	3,608,806	-	*
Smithfield Fiduciary LLC(5)	2,165,284	4.96	2,165,284	-	*
Nite Capital, LP(6)	3,337,044	5.37	2,887,044	-	*
Cyrille F. Buhrman	3,608,806	1.22	3,608,806	-	*
Ed Burke	811,982	1.10	811,982	-	*
Little Gem Life Sciences Fund, LLC(7)	721,762	*	721,762	-	*
Steven Mark	180,440	*	180,440	-	*
Vasili Myrianthopoulos	144,352	*	144,352	-	*
Kim Alberstadt	72,176	*	72,176	-	*
Evan Myrianthopoulos	180,440	*	180,440	-	*
Mike Sember	360,880	*	360,880	-	*
David Gentile	120,288	*	120,288	-	*

Bernard Pismeny	120,288	*	120,288	-	*
Kyle Brengel	120,288	*	120,288	-	*
Bristol Investment Fund, Ltd.(8)	1,804,402	2.72	1,804,402	-	*
Midsouth Capital, Inc.(9)	1,901,196	2.83	1,271,488	-	*
Nicholas Stergis	1,350,000	2.06	1,350,000	-	*
Baruch Ruttner	1,350,000	2.06	1,350,000	-	*
David Tanen	184,091	*	184,091	-	*
Michael Ferrari	76,705	*	76,705	-	*
Ham Park	76,705	*	76,705	-	*
Sarah Laut	30,682	*	30,682	-	*

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* 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 May 5, 2006, 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 65,395,814 shares of common stock outstanding as of May 5, 2006.

(1) The shares of common stock issuable upon the exercise of warrants as follows: Iroquois Master Fund LTD, 2,526,164 shares; Platinum Partners Long Term Growth III, 2,165,283 shares; Alpha Capital AG/CO / LH Financial, 1,804,403 shares; Smithfield Fiduciary LLC / Highbridge Capital Management, LLC, 1,082,642 shares; Nite Capital, LP, 1,893,522 shares; Cyrille F. Buhrman, 1,804,403 shares; Ed Burke, 451,101 shares; Little Gem Life Sciences Fund, LLC 360,881 shares; Steven Mark, 90,220 shares; Vasili Myrianthopoulos, 72,176 shares; Kim Alberstadt 36,088 shares; Evan Myrianthopoulos, 90,220 shares; Mike Sember, 180,440 shares; David Gentile, 60,144 shares; Bernard Pismeny, 60,144 shares; Kyle Brengel, 60,144 shares; Bristol Capitol Advisors, LLC, 902,201 shares and Midsouth Capital Inc., 1,901,196 shares.

(2) Joshua Silverman is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Iroquois Master Fund LTD. Iroquois Master Fund LTD is not a broker dealer, nor is it affiliated with one.

(3) Mark Norducht is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Platinum Partners Long Term Growth III. Platinum Partners Long Term Growth III is not a broker dealer, nor is it affiliated with one.

(4) Konrad Ackerman is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Alpha Capital AG/CO / LH Financial. Alpha Capital AG/CO / LH Financial are not broker

dealers, nor they affiliated with one.

(5) Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC. Glenn Dubin and Henry Swieca control Highbridge Capital Management, LLC and as such are the natural persons who exercise shared voting or dispositive power with respect to the shares held of record by Smithfield Fiduciary LLC. Each of Highbridge Capital Management, LLC, Glenn Dubin and Henry Swieca disclaim beneficial ownership of the securities held by Smithfield Fiduciary LLC. Smithfield Fiduciary LLC and Highbridge Capital Management, LLC are not broker dealers, nor are they affiliated with one.

(6) Keith Goodman is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Nile Capital, LP. Mr. Goodman disclaims beneficial ownership of these securities. Nile Capital, LP is not a broker dealer, nor is it affiliated with one.

(7) Jeffrey Benison is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Little Gem Life Sciences Fund, LLC. Little Gem Life Sciences Fund, LLC is not a broker dealer, nor is it affiliated with one.

(8) Bristol Capital Advisors, LLC is the investment advisor to Bristol Investment Fund, Ltd. Paul Kessler is the manager of Bristol Capital Advisors, LLC and as such is the natural person who exercises sole voting or dispositive power with respect to the shares held of record by Bristol Investment Fund, Ltd. Mr. Kessler disclaims beneficial ownership of these securities. Bristol Investment Fund, Ltd. is not a broker dealer, nor is it affiliated with one.

(9) MidSouth Capital, Inc. is a broker-dealer who acted as placement agent for the private placement completed on April 10, 2006.

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 approximately $6.3 million in proceeds from the exercise of the Warrants to purchase our common stock. We intend to use the net proceeds from the exercise of the Warrants as working capital to cover costs associated with the assembly and filing of the NDA for orBec®, other research and development expenses, and general overhead costs including salaries until such time, if ever, as we are able to generate a positive cash flow from operation.

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits investors;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- to cover short sales and other hedging transactions made after the date that the registration statement of which this prospectus is a part is declared effective by the Securities and Exchange Commission;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the investor of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon our being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference

in this prospectus, and (vi) other facts material to the transaction. In addition, upon our being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, that can be attributed to the sale of securities will be paid by the selling stockholders and/or the purchasers of the securities.

Each selling stockholder that is affiliated with a registered broker-dealer has confirmed to us that, at the time it acquired the securities subject to the registration statement of which this prospectus is a part; it did not have any agreement or understanding, directly or indirectly, with any person to distribute any of such securities. The Company has advised each selling stockholder that it may not use shares registered on the registration statement of which this prospectus is a part to cover short sales of our common stock made prior to the date on which such registration statement was declared effective by the SEC.

We are required to pay certain fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect and (ii) such time as all of the shares have been publicly sold.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 155,000,000 shares of capital stock, of which 150,000,000 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 $.05 per share and 200,000 shares are Series C Convertible Preferred Stock, par value $0.05 per share. As of May 5, 2006, there were issued and outstanding 65,395,814 shares of common stock, options to purchase 9,826,838 shares of common stock and warrants to purchase 36,628,789 shares of common stock. The amount outstanding includes the 13,099,964 shares of common stock issued to the Selling Stockholders.

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.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is presently 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, in each quarter for the period from January 1, 2004 through March 31, 2006. Until April 18, 2006, our common stock was listed on the American Stock Exchange. The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

	Price Range	
Period	**High**	**Low**
Fiscal Year Ended December 31, 2004:		
First Quarter	$1.58	$0.70
Second Quarter	$0.97	$0.53
Third Quarter	$0.65	$0.36
Fourth Quarter	$0.81	$0.41
Fiscal Year Ended December 31, 2005:		
First Quarter	$0.67	$0.35
Second Quarter	$0.42	$0.29
Third Quarter	$0.45	$0.32
Fourth Quarter	$0.36	$0.22
Fiscal Year Ended December 31, 2006:		
First Quarter	$0.69	$0.26

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of May 5, 2006, the last reported price of our common stock quoted on the OTCBB was $0.32 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 1,083 registered holders of record.

Dividend Policy

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

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 herein in the Registration Statement have been audited by Sweeney, Gates & Co., an independent registered public accounting firm, for the years ended December 31, 2005 and 2004 as set forth in their report appearing herein and elsewhere in the Registration Statement. 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 Stockholder will be passed upon by the law firm of Edwards Angell Palmer & Dodge LLP, Fort Lauderdale, Florida.

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DOR BIOPHARMA, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements—December 31, 2005 and 2004:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of DOR BioPharma, Inc. and subsidiaries at December 31, 2005 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years ended December 31, 2005 and 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company, as of December 31, 2005 and the results of its operations and its cash flows for the years ended December 31, 2005 and 2004, in conformity with United States generally accepted accounting principals.

Sweeney, Gates & Co.

Fort Lauderdale, Florida
March 17, 2006

DOR BioPharma, Inc.
Consolidated Balance Sheet
December 31, 2005

Assets	
Current assets:	
Cash and cash equivalents	**$ 821,702**
Grants receivable	**564,330**
Prepaid expenses	**138,794**
Total current assets	**1,524,826**
Office and laboratory equipment, net	**44,728**
Intangible assets, net	**1,803,020**
Total assets	**$ 3,372,574**
Liabilities and shareholders' equity	
Current liabilities:	
Accounts payable	**$ 1,530,900**
Accrued royalties	**60,000**
Accrued compensation	**148,601**
Accrued other expenses	**105,000**
Total current liabilities	**1,844,501**
Shareholders' equity:	
Common stock, $.001 par value. Authorized 150,000,000	
shares; 50,612,504 issued and outstanding	**50,612**
Additional paid-in capital	**86,045,192**
Accumulated deficit	**(84,567,731)**
Total shareholders' equity	**1,528,073**
Total liabilities and shareholders' equity	**$ 3,372,574**

The accompanying notes are an integral part of these financial statements

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

	2005	2004
Revenues	**$ 3,075,736**	$ 997,4827,
Cost of revenues	**(2,067,034)**	(936,6366)
Gross profit	**1,008,702**	60,8466
Operating expenses:		
Research and development	**3,681,137**	3,656,7766
General and administrative	**2,162,616**	2,321,1866
Total operating expenses	**5,843,753**	5,977,9622
Loss from operations	**(4,835,051)**	(5,917,1166)
Other income (expense):		
Interest income	**78,242**	66,539
Interest (expense) reversal	**36,549**	(20,997)
Total other income (expense)	**114,791**	45,542
Net loss	**(4,720,260)**	(5,871,574)
Preferred stock dividends	**-**	(503,195)
Net loss applicable to common shareholders	**$(4,720,260)**	$(6,374,769)
Basic and diluted net loss per share applicable to common shareholders	**$ (0.09)**	$ (0.16)
Basic and diluted weighted average common shares outstanding	**49,726,249**	40,626,621

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2005 and 2004

	Series B Preferred Stock		Common Stock		Additional Paid-In capital	Accumulated Deficit	Treasury Stock	
	Shares	Stated Value	Shares	Par Value			Shares	Cost
Balance, January 1, 2004	126,488	$12,648,768	34,893,765	$ 34,894	$67,005,276	($73,975,897)	172,342	($468,267)
Issuance of common stock, from private placement	-	-	4,113,925	4,114	3,039,870	-	-	-
Conversion of preferred stock to common stock	(128,203)	(12,820,303)	2,886,438	2,886	12,817,417	-	-	-
Exercise of shares from options or warrants	-	-	377,976	378	104,269	-	-	-
Preferred stock dividends	1,715	171,535	-	-	(171,535)	-	-	-
Non-cash compensation	-	-	-		467,183	-	-	
Purchase of treasury stock	-	-	-		-	-	2,000	(1,316)
Treasury stock retired	-	-	(53,700)	(54)	(41,832)	-	(53,700)	41,886
Net loss	-	-	-		-	(5,871,574)	-	
Balance, December 31, 2004	-	$ -	42,218,404	$ 42,218	$83,216,533	($79,847,471)	120,642	($427,697)
Issuance of common	-	-	8,396,100	8,396	3,539,897	-	-	-

stock, from private placement								
Treasury stock retired	**-**	**-**	**(2,000)**	**(2)**	**(426,383)**	**-**	**(120,642)**	**427,697**
Reversal of non-cash compensation	**-**	**-**	**-**	**-**	**(284,855)**	**-**	**-**	**-**
Net loss	**-**	**-**	**-**	**-**	**-**	**4,720,260**	**-**	**-**
Balance, December 31, 2005	**-**	**$ -**	**50,612,504**	**$ 50,612**	**$86,045,192**	**($84,567,731)**	**-**	**$ -**

The accompanying notes are an integral part of these financial statements

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

	2005	2004
Operating activities:		
Net loss	**$ (4,720,260)**	$ (5,871,574)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	**194,284**	296,234
Impairment expense for intangibles	**164,346**	6,215
Non-cash stock compensation	**(284,855**)	467,183
Change in operating assets and liabilities:		
Grants receivable	**178,657**	(722,033)
Prepaid expenses	**(79,191**)	96,240
Accounts payable	**(167,039**)	1,457,371
Accrued royalties	**(40,000**)	(220,000)
Accrued compensation and other expenses	**83,356**	82,588
Total adjustments	**49,558**	1,463,798
Net cash used by operating activities	**(4,670,702**)	(4,407,776)
Investing activities:		
Purchases of office and laboratory equipment	**(21,561**)	(10,559)
Acquisition of intangible assets	**(250,570**)	(267,096)
Net cash used by investing activities	**(272,131**)	(277,655)
Financing activities:		
Repayments of note payable	**(115,948)**	(243,119)
Net proceeds from issuance of common stock	**3,548,293**	3,039,870
Proceeds from exercise of options	**-**	104,647
Purchases of common stock for treasury	**-**	(1,316)
Net cash provided by financing activities	**3,432,345**	2,900,082
Net (decrease) in cash and cash equivalents	**(1,510,488**	(1,785,349
Cash and cash equivalents at beginning of period	**2,332,190**	4,117,539
Cash and cash equivalents at end of period	**$ 821,702**	$ 2,332,190
Supplemental disclosure of cash flow:		
Cash paid for interest	**$ 41,865**	$ 3,383
Non-cash transactions:		
Non-cash stock option expense (reversal)	**$(284,855)**	$ 393,913
Issuance of preferred stock dividend in kind	-	$ 171,535
Issuance of common stock for intangible assets	-	$ 32,778
Options for increase in subsidiary ownership	-	$ 88,740
	-	$ 331,660

Issuance of common stock to induce preferred stock conversion	

The accompanying notes are an integral part of these financial statements

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Organization and Nature of Business

Nature of Business

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

During the year ending December 31, 2005, the Company had one customer, the U.S. Federal Government. All revenues were generated from two U.S. Federal Government Grants. As of December 31, 2005 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration.

Principles of Consolidation

The consolidated financial statements include DOR BioPharma Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). The Company owns a 89.13% interest in Enteron Pharmaceuticals, Inc., its subsidiary developing orBec® All significant intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Segment Information

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less when purchased to be cash equivalents.

Grants Receivable

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

Intangible Assets

Intangible assets consist of patent costs, principally legal fees, and, upon application for the patent, are amortized on a straight-line basis over the shorter of the estimated useful life of the patent or the regulatory life

Impairment of Long-Lived Assets

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

The Company recorded impairment of intangible assets of $164,346 and $6,215 for the years ended December 31, 2005 and 2004, respectively.

Fair Value of Financial Instruments

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

Revenue Recognition

The Company recognizes revenue from government grants. These revenues are recorded in the period in which they are earned. The consideration received is based upon a cost plus Facilities and Administrative (F&A) rate that provides funding for overhead expenses. Similar to many cost-reimbursable grants, these governmental grants are typically subject to audit and adjustment by the government.

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.

Stock Based Compensation

The Company has stock-based compensation plans. SFAS No. 123, "Accounting for Stock-Based Compensation," encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has chosen to continue using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, in accounting for its stock option plans. In December 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard SFAS No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure" which amends SFAS No. 123 "Accounting for Stock-Based Compensation." Had compensation cost been determined based upon the fair value at the grant date for awards under the plans based on the provisions of SFAS No. 123, the Company's SFAS No. 123 pro forma net loss and net loss per share would have been as follows:

December 31,		
	2005	2004
Net loss applicable to common shareholders		
As reported	**$ (4,720,260)**	$ (6,374,769)
Add stock-based employee compensation expense related to stock options determined under fair value method	**(393,226)**	(1,023,368)
Amounts (credited) charged to income	**(284,855)**	284,855
Pro forma net loss according to SFAS 123	**$ (5,398,341)**	$ (7,113,282)
Net loss per share:		
As reported, basic and diluted	**$ (0 .09)**	$ (0 .16)
Pro forma, basic and diluted	**$ (0 .11)**	$ (0 .18)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.48 and $0.44 for 2005 and 2004, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 121% and 129% in 2005 and 2004, respectively and average risk-free interest rates in 2005 and 2004 of 3.75% and 3.5%, respectively.

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is periodically remeasured as the options vest.

Income Taxes

The Company files a consolidated federal income tax return and utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2005 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

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

Use of Estimates and Assumptions

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

New Accounting Pronouncements

On December 16, 2004, the FASB issued Statement No. 123R, "Share-Based Payment" which requires companies to record compensation expense for stock options issued to employees at an amount determined by the fair value of the options. SFAS No. 123R is effective for interim or annual periods beginning after June 15, 2005. As such, effective with the Company's first fiscal quarter of 2006, SFAS No. 123R will eliminate the Company's ability to account for stock options using the method permitted under APB 25 and instead require us to recognize compensation expense should the Company issue options to its employees or non-employee directors. The Company will adopt this policy effective January 1, 2006 and is in the process of evaluating the impact adoption of will have on the consolidated financial statements.

In December 2004, the FASB issued SEAS No. 153, "Exchange of Non-monetary Assets, an amendment of APB Opinion No 29, Accounting for Non-monetary Transactions". SFAS No. 153 eliminates the exception for non-monetary exchanges of similar productive assets, which were previously required to be recorded on a carryover basis rather than a fair value basis. Instead, this statement provides that exchanges of non-monetary assets that do not have commercial substance be reported at carryover basis rather than a fair value basis. A non-monetary exchange is considered to have commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The Company expects to adopt the standard during the fiscal year 2006. The Company is evaluating the requirements of SFAS No. 153 and has not determined the impact on its financial condition or results of operations.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" which provides guidance on the accounting for and reporting of accounting changes and correction of errors. This statement changes the

requirements for the accounting for and reporting of a change in accounting principle and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of this standard is not expected to have a material effect on the Company's results of operations or financial position.

3. **Liquidity and Management's Plan**

The Company has incurred continuing losses since its inception in 1987. At December 31, 2005 the Company had negative working capital of $319,675, a net loss of $4,720,260 and was delinquent in its payment of some of its obligations. The Company expects to sustain additional losses in 2006. Due to insufficient equity to meet American Stock Exchange requirements, the Company expects to be delisted from the Exchange on or shortly after March 31, 2006. This may adversely affect the ability of the Company to raise equity or debt capital. Moreover, the Company's ability to raise additional funding may be compromised should the Food and Drug Administration deny initial approval of orBec for sale in the United States.

Management's plan to generate positive cash flows either from operations or financing includes the following:

- In January 2006, the Company entered into a $6,000,000, 15 month equity financing agreement with an institutional investor to fund operations through the first quarter of 2007. This agreement provides for the sale of $20,000 of common stock per working day (the amount can be increased if the stock price is greater than $0.40). The stock price must be greater than $0.12 in order to use the financing agreement. According to the Company's management, this funding will be sufficient for research and administration through this period.
    - The Company plans to continue seeking sources for additional equity financing.
- The Company has taken steps to be traded on the Over the Counter ("OTC") bulletin board. Participation in the OTC bulletin board requires compliance with all SEC filing requirements.
    - The Company plans to continue seeking grant funds from governmental sources.
- The Company believes that if there were no other sources of financing and it is not able to utilize the funding from the investment banking organization, reductions or discontinued operations of several of the Company's programs may be required. If this should occur, the Company believes it could continue to operate over the next four quarters at a reduced level and only continue with the existing NIH and FDA grant projects.
    - The Company is also exploring outlicensing opportunities for its BioTherapeutic and BioDefense programs.

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

4. Office and Laboratory Equipment

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

	December 31,	
	2005	2004
Office equipment	**$ 115,108**	$ 95,417
Laboratory equipment	**23,212**	23,212
Total	**138,320**	118,629
Accumulated depreciation	**(93,592)**	(68,149)
	$ 44,728	$ 50,480

Depreciation expense was $25,443 and $20,875 for the years ended December 31, 2005 and 2004, respectively.

5. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2005	10.2	$ 2,605,472	$ 802,452	$ 1,803,020
December 31, 2004	10.6	$ 2,611,195	$ 728,741	$ 1,882,454

Amortization expense was $168,841 and $302,449 for 2005 and 2004, respectively.

Based on the balance of licenses and patents at December 31, 2004, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Amount
2006	$ 170,000
2007	170,000
2008	170,000
2009	170,000
2010	170,000

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

In July 2003, the Company entered into an exclusive license agreement with University of Texas South Western (UTSW) for administering the ricin vaccine via the intramuscular route for initial license fees of 250,000 shares valued at $200,000 of DOR common stock and $200,000 in cash. Subsequently, the Company negotiated the remaining intranasal and oral rights to the ricin vaccine for $50,000 in annual license fees in subsequent years. On March 1, 2005 the Company signed a sponsored research agreement with UTSW extending through March 31, 2007. For $190,000 UTSW will grant the Company certain rights to intellectual property.

In October 2003, the Company executed an exclusive license agreement with the University of Texas System (UTMB) for the use luminally-active steroids, including beclomethasone dipropionate (BDP) in the treatment of irritable bowel syndrome. Pursuant to this agreement the Company paid UTMB a license fee of $10,000 and also agreed to pay an additional $10,000 license fee expense each year. The Company also agreed to pay past and future patent maintenance costs. The cost for 2005 and 2004 was $12,728 and $39,171, respectively. The Company acquired a sublicense agreement and may receive payments on this sublicense in the event of the sublicensee reaching certain milestones.

Upon execution of a royalty bearing license agreement to a pharmaceutical company in July 2003, the Company paid an additional license fee of $175,000 for the encapsulation of antigens in polymeric microspheres and their use in oral or mucosal vaccination primarily in the use of a vaccine for ricin. The Company also agreed to provide $130,000 of sponsored research during 2003, a $60,000 annual license fee and $60,000 annually for patent maintenance.

In July 2005 the Company signed a sponsored research agreement with Thomas Jefferson University (TJU) that would pay TJU $150,000. In May 2003, the Company signed a license agreement with TJU for the licensure of detoxified botulinum toxin for use as a vaccine. The Company paid TJU $30,000 in cash and issued 141,305 shares of common stock valued at $130,000. The Company also agreed to reimburse TJU for past and future patent maintenance. The

patent maintenance expense for 2005 and 2004 was $157,293 and $58,922, respectively. The patent costs are capitalized. The Company is also responsible for a license maintenance fee of $10,000 in 2004 and 2005 and $15,000 in 2005 and each year thereafter. These costs are expensed as incurred. The Company is also responsible for paying TJU $200,000 upon the first filing of any New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") and $400,000 upon first approval of an NDA relating to the first licensed product by FDA.

6. Notes Payable

On June 29, 2002, DOR and a pharmaceutical company signed an agreement for the dissolution of their joint ventures. Based on this agreement, DOR retained the joint venture entities, InnoVaccines and Newco. In connection with the settlement, the Company's balance of $2,042,833 due to joint ventures at December 31, 2001 was restructured into payments totaling $1,104,242: $524,500 paid immediately in cash and the remaining $579,742 payments of principal and interest of $231,897 were due on June 30, 2003, $231,897 on June 30, 2004 and $115,948 on December 30, 2004, respectively.

The note payable of $115,948 was paid in the third quarter of 2005. DOR paid the principal balance in full and 50% of the interest accrued as full payment. The total payment of principal and interest was $157,813. This resulted in a reversal of interest previously accrued and expensed of $41,864.

7. Shareholders' Equity

Preferred Stock

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

In 1998, a pharmaceutical company purchased $8,000,000 of DOR Series B convertible preferred stock, which was convertible into common stock at a price of $5.11 per share, subject to adjustment, with automatic conversion at such point that the common stock traded over 100,000 shares per day at a closing price of at least $9.75 per share for 20 out of 30 consecutive trading days. In the intervening years, the Company issued additional preferred shares and stock dividends. The Series B convertible preferred stock paid an 8% annual in-kind dividend, which was valued at $171,535 in 2004. The Company issued 1715 shares of preferred stock. In March 2004, the Company issued the pharmaceutical company 376,886 shares of common stock valued at $331,660, as an inducement for the early conversion and exchanged 128,203 shares of Series B of preferred stock for 2,509,552 shares of common stock.

Common Stock

In February 2005, the Company sold 8,396,100 shares of common stock at $0.45 per share for proceeds, net of expenses, of $3,548,293 in a private placement to institutional investors. Investors also received warrants to purchase 6,297,075 shares of common stock at an exercise price of $0.505 per share. These warrants expire on August 8, 2010 and are callable when the price reaches $1.52 for 20 consecutive days. The placement agent was paid cash $188,912, and warrants to purchase 629,708 shares of the Company's common stock exercisable by August 8, 2010 at $0.625. The warrants are callable when the price reaches $1.88 for 20 consecutive days.

In 2005, the Company retired 120,640 shares of treasury stock.

During 2004, individuals exercised common stock options and common stock warrants at various prices from $0.20 to $0.75 for total proceeds of $104,647.

In March 2004, the Company sold 4,113,925 shares of common stock in a private placement. Gross proceeds were $3,250,000 (net after commissions and expenses, $3,039,870). In addition to common stock, for each share purchased

investors received a warrant to purchase .4 shares of common stock, for a total of 1,645,570, exercisable at $0.87 per share until the earlier of an average closing price for 20 consecutive days of the Company's common stock of $1.74 per share or March 15, 2009. The placement agent was paid cash compensation of approximately $162,500, and issued warrants to purchase 287,974 shares of the Company's common stock exercisable for five years at $0.87 per share.

In September 2004, the Company retired 53,700 shares of treasury stock.

Stock Compensation to Non-employees

During 2004, the Company issued 46,886 warrants to purchase common stock valued at $32,778 to a University for license agreements.

During 2004, the Company issued 50,000 stock options to 3 resigning directors. The grants were valued at $20,270 each, for a total of $60,810.

During 2004, the Company issued 200,000 warrants to purchase common stock valued at $88,740 to a consultant, in exchange for his 160,000 shares of Enteron stock. In addition, contingent warrants were issued to a consultant. A consultant was issued 400,000 warrants to purchase common stock for consulting services with an expiration date of April 2009 and will be exercisable on the approval date for orBec®.

In 2004, the Company granted options to employees and directors that were conditional upon stockholder approval of an amendment to the 1995 Omnibus Plan. Therefore, a measurement date did not exist at the approval date. This resulted in an expense of approximately $285,000. The expense was reversed when the Company received approval of its 2005 Equity Incentive Plan. The Plan granted 10,000,000 shares of Common Stock to issue for satisfaction of awards made under the 2005 Equity Incentive Plan.

8. Stock Option Plans and Warrants

The 2005 Equity Incentive Plan is divided into four separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

	December 31,	
	2005	2004
Shares available for grant at beginning of year	**(1,979,339)**	1,630,587
Increase in shares available	**10,000,000**	-
Options granted	**(3,500,000)**	(4,500,000)
Options exercised	**-**	240,000
Options forfeited or expired	**2,479,339**	650,074
Shares available for grant at end of year	**7,000,000**	(1,979,339)

In 2004 the Company granted options to employees and directors that were conditional upon stockholder approval of an amendment to the 1995 Omnibus Option Plan. Accordingly, a measurement date did not exist at the approval date. The Company recorded an expense of approximately $285,000. This expense was reversed in 2005.

Option activity for the years ended December 31, 2005 and 2004 was as follows:

	Options	**Weighted Average Options Exercise Price**
Balance at January 1, 2004	7,889,413	$ 0.72
Granted	4,500,000	0.49
Forfeited	(650,074)	0.78
Exercised	240,000	0.20
Balance at December 31, 2004	**11,979,339**	**0.64**
Granted	500,000	0.41
Forfeited	(2,465,000)	0.83
Balance at December 31, 2005	**10,014,339**	**$ 0.59**

The weighted-average exercise price, by price range, for outstanding options at December 31, 2005 was:

Price Range	**Weighted Average Remaining Contractual Life in Years**	**Outstanding Options**	**Exercisable Options**
$0.20-$0.50	6.61	7,310,000	5,767,499
$0.51-$1.00	5.69	2,362,839	2,262,839
$1.01-$6.00	3.89	541,500	541,500
Total	**6.25**	**10,214,339**	**8,571,838**

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

Warrant activity for the years ended December 31, 2005 and 2004 was as follows:

	Options	Weighted Average Warrant Exercise Price
Balance at January 1, 2004	12,207,523	$ 1.37
Granted	2,580,429	0.80
Balance at December 31, 2004	**14,787,952**	**1.24**
Granted	6,926,783	0.52
Expired	(452,383)	5.91
Balance at December 31, 2005	**22,167,118**	**$ 0.92**

The weighted-average exercise price, by price range, for outstanding options at December 31, 2005 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.35-$0.75	3.97	9,579,503	9,579,503
$0.76-$1.50	2.81	10,141,733	10,141,733
$1.51-$8.50	2.29	2,445,882	2,445,882
Total	**3.26**	**22,167,118**	**22,167,118**

9. Income Taxes

The types of temporary differences between tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax asset (liability) and their approximate tax effects are as follows:

	December 31,	
	2005	2004
Deferred tax assets:		
Net operating loss carryforwards	**$ 23,260,000**	$ 21,524,000
Orphan drug credit carryforwards	**1,944,000**	1,894,000
Research and development credit carryforwards	**752,000**	693,000
Work opportunity credit carryforwards	**260,000**	260,000
Employee Retention Credit	**2,000**	-
Total	**26,218,000**	24,371,000
Valuation allowance	**(26,218,000)**	(24,371,000)
Net deferred tax assets	**$ -**	$ -

At December 31, 2005, the Company had net operating loss carryforwards of approximately $59,800,000 for Federal and state tax purposes, which are currently expiring each year until 2025.

The following is the approximate amount of the Company's net operating losses that expire over the next five years:

2006	$ 222,000
2007	981,000
2008	910,000
2009	1,609,000
2010	