DOR BIOPHARMA INC
Form 424B3
April 17, 2009

Filed Purstuant to Rule 424(b)(3)

Registration No. 333-157322

PROSPECTUS

DOR BioPharma, Inc.

44,491,610 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 44,491,610 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 private placement in which we issued to certain of the Selling Stockholders an aggregate of 20,914,035 shares of our common stock, together with warrants to purchase up to 914,035 shares of our common stock. We also issued 16,666,667 shares of our common stock to one of the Selling Stockholders in connection with the execution of a letter of intent. In addition, we issued 2,713,539 shares of our common stock to certain of the Selling Stockholders as compensation for services rendered to us, warrants to purchase up to 1,000,000 shares of our common stock for a finder's fee and warrants to purchase up to 1,450,000 shares of our common stock for services rendered. We may issue 833,334 shares of our common stock to one of the Selling Stockholders as payment for services to be rendered to us. 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.OB." On April 9, 2009, the last reported sale price for our common stock as quoted on the OTCBB was $0.11 per share.

Investing in our common stock involves certain risks. See "Risk Factors" beginning on page 4 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.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

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The date of this prospectus is April 17, 2009.

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

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

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

FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements. These forward-looking statements are often identified by words such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue,” “plan” and similar expressions. These statement 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;
- our ability to execute and successfully complete the upcoming confirmatory Phase 3 clinical trial of orBec® for the treatment of gastrointestinal Graft-versus-Host disease;
- the possibility that orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- our dependence on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;
- the possibility that orBec® may not gain market acceptance; and
- that 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

About Our Company

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

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

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

BioTherapeutic Products

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

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Biodefense Products

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

The consolidated financial statements for the year ended December 31, 2008, and reported in our annual report for the same period, were prepared assuming that we will continue as a going concern. Our ability to continue our operations is dependent on our ability to raise sufficient capital. Since December 31, 2008, we have raised an additional $8,384,200 through equity financings. We believe that this funding will allow us to continue operations into the third quarter of 2010.

Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is 609-538-8200.

The Offering

This prospectus relates to the offer and sale, from time to time, of up 44,491,610 shares of our common stock 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.

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

As of April 9, 2009, there were 167,070,944 shares outstanding, including 40,294,241 of the 44,491,610 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus represents approximately 26.63% of the total common stock outstanding as of April 9, 2009.

RISK FACTORS

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

Risks Related to our Industry

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

We have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2008, we had $1,475,466 in cash available. Since December 31, 2008, we have issued a total of 62,580,702 shares of common stock and warrants to purchase up to 20,914,035 shares of common stock raising a sum of $8,384,200. Based on our projected budgetary needs and funding from the existing grants over the next 18 months, we expect to be able to maintain the current level of our operations into the third quarter of 2010 and conduct the pivotal Phase 3 confirmatory clinical trial of orBec® for the treatment of acute GI GVHD.

We have sufficient funds through our existing, biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institute of Health (“NIH”) to finance our biodefense projects. On September 29, 2006, we announced that we had received approximately $5,300,000 in grants for the development of our biodefense programs. Our biodefense grants have an overhead component that allows us an agency approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses and includes funds for direct employees working on the grants, from our existing NIH biodefense grants will generate approximately $600,000 over the next four quarters.

Our products are positioned for or are currently in preclinical studies or clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. Through December 31, 2008, we had expended approximately $24,200,000 developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $9 million over the next two years in connection with the development and commercialization of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our lead product candidate, or another one of our product candidates, we will require additional funding through our existing equity facility with Fusion Capital Fund II, LLC (“Fusion Capital”) or another financing source to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and preclinical development and will require significant further funding, research, development,

preclinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

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

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

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

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

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

On October 18, 2007, we received a not approvable letter from the FDA for our lead product candidate, orBec®, for the treatment of acute GI GVHD. The letter stated that the FDA requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an “End of Review Conference” with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipated working quickly with the FDA to finalize the design of the confirmatory trial under the Agency’s “Special Protocol Assessment” process; and (3) the FDA would be agreeable to reviewing a plan for a Treatment Investigational New Drug ("Treatment IND") as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study.

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

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

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

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

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

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccines we are developing are safe in

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

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

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

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

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

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

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain

compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

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

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. Although we have a collaboration agreement with Sigma-Tau for the sales and marketing of orBec® in North America, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In Addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

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

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

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

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

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

products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America or enter into an agreement for the commercialization of orBec® with another Company. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

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

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

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

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

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

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

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

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

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

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

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

We have only nine employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Dr. Christopher J. Schaber, our Chief Executive Officer, was hired in August 2006; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was a member of our Board of Directors for two years prior to that; Dr. Robert Brey, our Chief Scientific Officer was hired in 1996; Dr. Brian L. Hamilton, our Chief Medical Officer, was hired in March 2009; and James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. In June 2007, Cyrille F. Buhrman was appointed to the Board of Directors. In March 2009, Gregg Lapointe was appointed to the Board of Directors. We will not be successful if this management team cannot effectively manage and operate our business. Several members

of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

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

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

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

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

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

Our stock price has fluctuated between January 1, 2005 through April 9, 2009 with the per share price of our common stock ranging between a high of $0.95 per share to a low of $0.04 per share. As of April 9, 2009, our common stock traded at $0.11. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

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

On April 18, 2006, our stock was delisted from the American Stock Exchange ("AMEX") and began trading on the OTCBB securities market on April 18, 2006 under the ticker symbol DORB. Our stock was delisted from the AMEX because we did not maintain stockholder equity above $6,000,000, as required under the maintenance requirement for continued listing. The OTCBB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies. On the OTCBB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCBB securities include national, regional, and foreign equity issues. Companies traded on the OTCBB must be current in their reports filed with the Securities and Exchange Commission (the "SEC") and other regulatory authorities.

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

Shareholders may suffer substantial dilution.

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

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

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

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

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

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

We already have sold 3,864,987 shares of common stock to Fusion Capital (together with a warrant to purchase 1,388,889 shares of our common stock) under the agreement for total proceeds of $627,500. Additionally, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In addition to the shares already sold to

Fusion Capital, we have filed a registration statement with respect to approximately 18.8 million shares that are available to be sold to Fusion Capital. We may ultimately sell all, some or none of the 18.8 million shares of common stock. If such 18.8 million shares were issued and outstanding as of April 9, 2009, the 18.8 million shares would have represented approximately 11.3% of the total outstanding common stock.

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

On February 14, 2008, we entered into an $8,500,000 common stock purchase agreement with Fusion Capital. The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million, depending on certain conditions, of our common stock up to an aggregate of $8.5 million over approximately a 25-month period. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock at $0.22 per share, for an aggregate price of $500,000. To date, we have issued an additional 1,012,209 shares of common stock and received an additional $127,500 from the Fusion Capital facility.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 25,327,778 shares registered for sale by Fusion Capital are freely tradable. It is anticipated that those shares will be sold over a period of up to 25 months from the date of the prospectus pertaining to those shares. Depending upon market liquidity at the time, a sale of shares under the registration statement at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the approximately 18.8 million shares of common stock not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

The common stock purchase agreement with Fusion Capital also may be terminated in the event of a default under the agreement. In addition, we cannot require Fusion Capital to purchase any shares of our common stock if the purchase price is less than $0.10 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. The closing price of our common stock on April 9, 2009 was $0.11.

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

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

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

THE COMPANY

Overview

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

(a) initiate and execute the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute gastrointestinal GI GVHD;
(b) identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico, Sigma-Tau will pay us a 35% roylaty on net sales in these territories as well as pay for commercialization expenses, including launch activities;
(c) conduct a Phase 2 clinical trial of orBec® for the prevention of acute GI GVHD;
(d) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as radiation enteritis, radiation injury and Crohn's disease;
(e) make orBec® available worldwide through NPAP for the treatment of acute GI GVHD;
(f) reinitiate development of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area;
(i) acquire or in-license new clinical-stage compounds for development; and
(j) explore other business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company.

Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is 609-538-8200.

BioTherapeutics Overview

orBec®

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

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

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Clinical and Regulatory History

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support orBec's® ability to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the US and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time to treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). At one year post randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p=0.04).

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

Based on the data from Phase 2 and the Phase 3 studies, on September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® with the U.S. Food and Drug Administration ("FDA") for the treatment of acute GI GVHD. On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") for orBec® with the European Central Authority, the European Medicines Evaluation Agency ("EMEA"). On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an "End of Review Conference" with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced FDA guidance from that meeting in which a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings, and that the FDA would be agreeable to reviewing a plan for a Treatment IND as long as it does not interfere with patient accrual in a confirmatory trial. In May 2008, we voluntarily withdrew the MAA that was being reviewed by EMEA. We reached this decision after consultation with the EMEA and determining that confirmatory evidence of clinical efficacy will be required for approval. This is consistent with the request made by the FDA. The withdrawal of an MAA application does not prejudice the possibility of making a new application at a later stage.

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

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

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

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

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On March 4, 2007, the Company entered into an investment banking agreement with RBC Capital Markets ("RBC"). As a result of the Company's transactions with Sigma-Tau, RBC claims that it is entitled to certain compensation under such agreement. Although RBC has indicated that it is willing to settle the matter for approximately $1.6 million, the Company disputes that RBC is entitled to any compensation for the Sigma-Tau transactions and will vigorously defend any lawsuit filed by RBC against the Company.

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

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

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

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

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

On February 15, 2008, we announced that we entered into a Letter of Intent with BL&H Co. Ltd. ("BL&H"), a specialty pharmaceutical company based in Seoul, Korea, pursuant to which BL&H will act as our sponsor with regard to the administration of an NPAP for orBec® to patients suffering from acute GI GVHD in South Korea.

On November 28, 2007, we announced that we entered into a Letter of Intent with Orphan Australia Pty Ltd. ("Orphan Australia"), a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which Orphan Australia will act as our sponsor with regard to the administration of an NPAP for orBec® to acute GI GVHD patients in Australia, New Zealand and South Africa.

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from NIH to conduct preclinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of GI radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this work is successful and it will enhance the value of our orBec®/oral BDP program. The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of first effects of radiation exposure. The rapid loss of epithelial

cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studies will compare overall survival and markers of intestinal cell regeneration when the drug regimens are added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC.

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

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orBec® Survival Results at 200 Days Post Transplantation

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

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

In this Phase 3 clinical trial, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, “the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p=0.03, Wald chi-square test).” The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

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

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

orBec® Comprehensive Long-Term Mortality Results

Among the data reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, orBec® showed continued survival benefit when compared to placebo one year after randomization in

the pivotal Phase 3 clinical trial. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p=0.04). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p=0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to orBec® compared with placebo (p=0.03).

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo.

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Commercialization and Market

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

On December 1, 2008, we received $1.5 million under a non-binding letter of intent with Sigma-Tau, which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. Sigma-Tau has both prescription and consumer products in the metabolic, oncology, and renal markets.

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

Research and Development Analysis for orBec®

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

About GVHD

GVHD occurs in patients following allogeneic bone marrow transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. will develop some form of acute GI GVHD.

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

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

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

the recipient patient.

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

Future Potential Indications of orBec® and Oral BDP

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

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DOR 201

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

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

About Acute Radiation Enteritis

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

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

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

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

BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin toxin vaccine to be clinically tested in humans. Ricin is a potent glycoprotein toxin derived from the beans of castor plants. It can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control ("CDC") has classified ricin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

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

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

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

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

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

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

In July 2007, we announced that the Office of Orphan Products Development ("OOPD") of the FDA has awarded a development grant for the further clinical evaluation of RiVaxTM. The grant was awarded to UTSW to further the development of RiVaxTM. We will not receive any monetary benefits from this grant; however, the successful completion of this work will enhance the value of our RiVaxTM program and continue to move it forward. The principal investigator for the project is Dr. Vitetta, Director of the Cancer Immunobiology Center at UTSW. The award totals approximately $940,000 for three years and is to be used for the evaluation of an adjuvant for use with the vaccine. Typically, awards made by the OOPD are to support clinical trials for development of products that address rare diseases or medicines that would be used in numerically small populations. UTSW began a second Phase 1 human clinical trial with RiVaxTM in August of 2008.

Research and Development Analysis for RiVax™

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

BT-VACC™

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

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

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

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

Research and Development Analysis for BT-VACC™

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

Anthrax Vaccine Option

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

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Additional Programs

LPMTM - Leuprolide

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

In preclinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising preclinical data, we anticipate preparing for a Phase 1 study in humans in 2009 to confirm these findings.

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

Research and Development Analysis for LPM™ Leuprolide

The costs that we have incurred to develop LPM™-Leuprolide since 2000 total approximately $1,400,000. Research and development costs for LPM™-Leuprolide totaled $112,246 for the 12 months ended December 31, 2008 and $38,254 and $5,679 for the years ended December 31, 2007 and 2006, respectively. These costs are mainly legal costs in connection with maintenance of our patent positions and for preclinical formulation work.

OraprineTM

We anticipate that an orally administered version of the immunosuppressant drug azathioprine may have a significant role in treating inflammatory diseases of the oral cavity. Further, an orally administered drug may provide a niche in the current transplant medicine market for an alternative to solid dosage forms of azathioprine that would have utility in elderly patients. OraprineTM is an oral suspension of azathioprine, which we believe may be bioequivalent to the oral azathioprine tablet currently marketed in the U.S. as Imuran®. We conducted a Phase 1 bioequivalence trial following a trial conducted by Dr. Joel Epstein at the University of Washington that established the feasibility of the

oral drug to treat oral ulcerative lesions resulting from GVHD. Oral GVHD can occur in up to 70% of patients who have undergone bone marrow/stem cell transplantation despite treatment with other immunosuppressive drugs such as prednisone, methotrexate, tacrolimus, and cyclosporine. Azathioprine is one of the most widely used immunosuppressive medications in clinical medicine. Azathioprine is commonly prescribed to organ transplant patients to decrease their natural defense mechanisms to foreign bodies (such as the transplanted organ). The decrease in the patient's immune system increases the chances of preventing rejection of the transplanted organ in the patient.

On September 25, 2007, we announced a Notice of Allowance of patent claims based on U.S. Patent Application #09/433,418 entitled "Topical Azathioprine for the Treatment of Oral Autoimmune Diseases." Concurrently, the patent has also been issued by the European Patent Office with the serial number EP 1 212 063 B1. This patent family specifically includes claims for treatment and prevention of oral GVHD with locally or topically applied azathioprine. We anticipate filing an ANDA; however this program is suspended pending further funding from financing or partnerships.

Research and Development Analysis for OraprineTM

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

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Summary of Our Products in Development

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

BioTherapeutic Products

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

Biodefense Products

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

The Drug Approval Process
General

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

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

An IND application is required before human clinical testing in the U.S. of a new drug compound or biological product can commence. The INDA includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

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

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

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

In the U.S., the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety,

labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the Federal Food, Drug, and Cosmetic Act involving medical devices.

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

Marketing Strategies

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

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

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

Competition

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

Biodefense Vaccine Competition

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

orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat GVHD by suppressing the immune system through various mechanisms. Some companies, including Sangstat, Abgenix, and Protein Design Labs, Inc., are developing monoclonal antibodies to treat GVHD. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat GVHD. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant related therapeutics. We face potential competition from Osiris

Therapeutics if their product Prochymal for the treatment of GVHD is successful in ongoing Phase 3 clinical trials and reaches market. Kiadis Pharma is also developing products for the treatment of GVHD. In addition, there are investigator-sponsored clinical trials exploring the use of approved drugs such as Enbrel®, which has been approved by the FDA for the treatment of rheumatoid arthritis, in the treatment of GVHD. We believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make orBec® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product RemicadeTM for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®. Entocort® is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In addition, Salix Pharmaceuticals, Inc. markets an FDA approved therapy for ulcerative colitis called Colazal®. Chiesi Pharmaceuticals ("Chiesi") markets a delayed release oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPERTM for ulcerative colitis and may seek marketing approval in Italy and other European countries. In the U.S., Eurand N.V. ("Eurand") has licenses from Chiesi to the same formulation as CLIPPERTM and is developing it for ulcerative colitis. Eurand has also received Orphan Drug Designation for the compound in pediatric ulcerative colitis patients.

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

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Patents and Other Proprietary Rights

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

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

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

orBec® License Agreement

In November 1998, our wholly-owned subsidiary, Enteron Pharmaceuticals, Inc. (“Enteron”), entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, M.D., including the right to grant sublicenses, for the rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDonald receives $80,000 per annum as a consultant.

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

Ricin Vaccine Intellectual Property

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

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

Botulinum Toxin Vaccine Intellectual Property

In 2003, we executed an exclusive license agreement with Thomas Jefferson University for issued U.S. Patent No. 6,051,239 and corresponding international patent applications broadly claiming the oral administration of nontoxic modified botulinum toxins as vaccines. The intellectual property also includes patent applications covering the inhaled and nasal routes of delivery of the vaccine. This license agreement required that we pay a license fee of $160,000, payable in $130,000 of common stock and $30,000 in cash. In 2003, we entered into a one-year sponsored research agreement with the execution of the license agreement with Thomas Jefferson University, renewable on an annual basis, under which we have provided $300,000 in annual research support. In addition, we also executed a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine for a period of three years. Under this agreement, Dr. Simpson received options to purchase 100,000 shares of our common stock, vesting over two years. We are also required to pay a $10,000 non-refundable license royalty fee no later than January 1 of each calendar year, which increased to $15,000 in 2006 and every year thereafter.

Description of Property

We currently lease approximately 5,250 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. The office space currently serves as our corporate headquarters. Pursuant to the lease dated April 1, 2009, we will pay rent of approximately $7,450 per month, or $17.00 per square foot per year, through October 2010. From November 2010 until the lease expires on March 31, 2012, we will pay rent of approximately $7,650, or $17.50 per square foot per year.

Employees

As of April 9, 2009, we had nine full-time employees, four of whom are Ph.D.s and one whom is also an M.D.

Research and Development Spending

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

Legal Proceedings

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 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 and our unaudited consolidated interim financial statements and their notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Forward-Looking Statements."

Business Overview and Strategy

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

Our business strategy is to:

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

Critical Accounting Policies

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

Intangible Assets

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

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

We capitalize and amortize intangibles over a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets.

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

We capitalize intangible assets that have alternative future uses as this is common practice in the pharmaceutical development industry. Of our intangible asset balance, our purchase of the RiVaxTM vaccine license from the University of Texas Southwestern Medical Center for $462,234 was for up-front license costs. We capitalize license costs because they have alternative future use as referred to in paragraph 11 c. of SFAS No.2. We believe that both of these intangible assets purchased have alternative future uses.

Research and Development Costs

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

Revenue Recognition

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

Stock Based Compensation

From time to time, we issue common stock to vendors, consultants, and employees as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

Stock based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

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Material Changes in Results of Operations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Financial Condition

Cash and Working Capital

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

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

Management's plan is as follows:

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

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

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

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

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

If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to

pursue certain courses of action. We may not be able to obtain such financing on acceptable terms if at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

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

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

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

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Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our expenditures for the next 12 months to be approximately $6,000,000. We anticipate grant revenues in the next 12 months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $2,000,000, with $600,000 contributing towards our overhead expenses.

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

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

Debt

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

Equity Transactions

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

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

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

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

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

On December 1, 2008, we entered into a non-binding letter of intent with Sigma-Tau, which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of our common stock at the market price of $0.09 per share, representing 16,666,667 shares.

On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital. The Fusion Capital facility allows us to require Fusion Capital to purchase between $80,000 and $1.0 million depending on certain conditions of our common stock up to an aggregate of $8.0 million over approximately a 25-month period. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. We issued 75,000 shares as a pro rata commitment fee in connection with the purchase of $500,000 of our common stock. If our stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of our common stock increases. We cannot require Fusion Capital to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.10 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 1,275,000 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 18.5 million shares.

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

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

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

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

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

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

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

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

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

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

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

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Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the fiscal year ended December 31, 2008 or the fiscal year ended December 31, 2007.

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DIRECTORS AND EXECUTIVE OFFICERS

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

Name	Age	Position
James S. Kuo, M.D., M.B.A.	45	Chairman of the Board
Cyrille F. Buhrman	36	Director
Gregg A. Lapointe, C.P.A., M.B.A.	50	Director
Christopher J. Schaber, Ph.D.	42	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	44	Chief Financial Officer, Senior Vice President, and Director
Brian L. Hamilton, M.D., Ph.D.	61	Chief Medical Officer, and Senior Vice President
Robert N. Brey, Ph.D.	58	Chief Scientific Officer, and Senior Vice President
James Clavijo, C.P.A., M.A.	43	Controller, Treasurer, and Corporate Secretary

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

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

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

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

B.A. degree from Western Maryland College, his M.S. degree in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. degree in Pharmaceutical Sciences from The Union Graduate School.

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

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

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

James Clavijo, C.P.A., M.A., has been with the Company since October 2004 and is currently our Controller, Treasurer, and Corporate Secretary. He brings 15 years of senior financial management experience, involving both domestic and international entities, and participating in over $100 million in equity and debt financing. Prior to

joining us, Mr. Clavijo held the position of Chief Financial Officer for Cigarette Racing Team (Miami, FL), from July 2003 to October 2004. During his time with Cigarette he was instrumental in developing a cost accounting manufacturing tracking system and managed the administration and development of an IRB Bond related to a 10 acre, 100,000 square foot facility purchase. Prior to joining Cigarette Racing Team, Mr. Clavijo held positions as Chief Financial Officer for Gallery Industries, from November 2001 to July 2003, a retail and manufacturing garment company. Prior to Gallery Industries, as Corporate Controller for A Novo Broadband, he managed several mergers and acquisitions and corporate restructuring. He also, held the position of Finance Manager for Wackenhut Corporation in the U.S. Governmental Services Division. In addition, he served in the U.S. Army from 1983 to 1996 in both a reserve and active duty capacity for personnel and medical units. Mr. Clavijo holds an M.A. degree in Accounting from Florida International University, a B.A. degree in Accounting from the University of Nebraska, and a B.S. degree in Chemistry from the University of Florida. Mr. Clavijo is a licensed Certified Public Accountant in the state of Florida.

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EXECUTIVE COMPENSATION

Summary Compensation

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

Summary Compensation Table

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

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

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

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

Potential Issuance of Shares

On February 28, 2007, our Board of Directors approved the issuance of 2,700,000 shares of our common stock to certain employees and a consultant to be issued immediately prior to the completion of a transaction, or series or

combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party (an "Acquisition Event"). Of the shares of common stock to be issued upon an Acquisition Event, 1,000,000 shares will be issued to Christopher J. Schaber, a director and our Chief Executive Officer and President; 750,000 shares will be issued to Evan Myrianthopoulos, a director and our Chief Financial Officer; and 300,000 shares will be issued to James Clavijo, our Controller, Treasurer, and Corporate Secretary.

Employment and Severance Agreements

During August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, Ph.D. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. This employment agreement was renewed in December 27, 2007 for a term of three years. We agreed to issue him options to purchase 2,500,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependants. No unvested options shall vest beyond the termination date.

Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) remained unchanged from 2006. He will be paid nine months severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

In December 2004, we entered into a three-year employment agreement with Mr. Myrianthopoulos. Pursuant to this employment agreement we agreed to pay Mr. Myrianthopoulos a base salary of $185,000 per year. After one year of service Mr. Myrianthopoulos would be entitled to a minimum annual bonus of $50,000. This employment agreement was renewed in December 27, 2007 for a term of three years. We agreed to issue him options to purchase 500,000 shares of our common stock, with the options vesting over three years. This option grant is subject to shareholder approval. Upon termination without "Just Cause" as defined by this agreement, we would pay Mr. Myrianthopoulos six months severance subject to set off, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. Mr. Myrianthopoulos also received 150,000 options, vested immediately when he was hired in November 2004, as President and Acting Chief Executive Officer.

Mr. Myrianthopoulos' monetary compensation (base salary of $200,000 and bonus of $50,000) remained unchanged from 2006. He will be paid six months severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Myrianthopoulos' options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become property of Mr. Myrianthopoulos' immediate family.

On March 27, 2009, the Compensation Committee approved the increase in salaries for: Dr. Schaber from $300,000 to $350,000; Mr. Myrianthopoulos from $200,000 to $230,000; and Dr. Brey from $190,000 to $200,000. Dr. Brey does not have an employment agreement.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber, Mr. Myrianthopoulos and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from the Company and/or our stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; and 200,000

common shares to Dr. Brey. The amended agreements include our obligation to issue such shares to the executives if such event occurs.

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2008. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber	2,083,343	416,657	416,657	$0.27	8/28/2016
	506,250	393,750	393,750	$0.47	8/29/2017
	700,000	2,100,000	2,100,000	$0.06	12/17/2018
Evan Myrianthopoulos	150,000	-	-	$0.35	11/14/2012
	50,000	-	-	$0.90	9/15/2013
	50,000	-	-	$0.58	6/11/2014
	150,000	-	-	$0.47	11/10/2014
	500,000	-	-	$0.49	12/13/2014
	375,000	25,000	25,000	$0.35	5/10/2016
	309,375	240,625	240,625	$0.47	8/29/2017
	300,000	900,000	900,000	$0.06	12/17/2018
Robert N. Brey	10,000	-	-	$2.00	2/23/2009
	9,000	-	-	$3.94	2/08/2010
	562,500	37,500	37,500	$0.33	5/10/2016
		75,000	75,000	$0.47	8/29/2017

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

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Compensation of Directors

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

Director Compensation

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

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

(2) We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 300,000 shares of common stock, and subsequent prorated annual grants of fully vested options to purchase 150,000 shares of common stock after re-election to our Board of Directors. During 2008, we did not hold an annual meeting. As a result there were no stock options granted to the Board of Directors in 2008. Option Awards include the value of stock option awards of vested shares of Common Stock as required by FASB No. 123R.

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the common stock as of April 9, 2009 of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

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

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of April 9, 2009 are deemed outstanding for

computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 167,070,944 shares of common stock outstanding as of April 9, 2009.

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

(2) Includes 20,000,000 shares of common stock and warrants to purchase 20,000,000 shares of common stock within 60 days of April 9, 2009. The address of Biotex Pharma Investments, LLC is c/o Biotex Pharma Investments, LLC, 220 West 42nd Street 6th Floor New York, NY 10036.

(3) Includes 4,900,020 shares of common stock and options to purchase 225,000 shares of common stock within 60 days of April 9, 2009. The address of Mr. Buhrman is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(4) Includes 392,766 shares of common stock owned by Dr. Schaber and options to purchase 3,715,983 shares of common stock within 60 days of April 9, 2009. The address of Dr. Schaber is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(5) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 2,053,125 shares of common stock and warrants to purchase 90,220 shares of common stock within 60 days of April 9, 2009. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(6) Includes options to purchase 1,019,000 shares of common stock within 60 days of April 9, 2009. The address of Dr. Brey is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(7) Includes 88,191 shares of common stock owned by Mr. Clavijo and options to purchase 862,500 shares of common stock within 60 days of April 9, 2009. The address of Mr. Clavijo is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(8) Includes options to purchase 625,000 shares of common stock and warrants to purchase 5,000 shares of common stock within 60 days of April 9, 2009. The address of Dr. Kuo is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(9) Includes options to purchase 300,000 shares of common stock within 60 days of April 9, 2009. The address of Mr. Lapointe is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(10) Includes options to purchase 250,000 shares of common stock within 60 days of April 9, 2009. The address of Dr. Hamilton is c/o DOR BioPharma, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

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Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2007, our stockholders approved an amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 10,000,000 shares, bringing the total shares reserved for issuance under the plan to 20,000,000 shares. The following table provides information, as of December 31, 2008, with respect to options outstanding under our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-Average Exercise Price Outstanding options, warrants and rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders (1)	16,370,039	$ 0.27	3,547,331
Equity compensation plans not approved by security holders	-	-	-
TOTAL	16,370,039	$0.27	3,547,331

(1) Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Our 1995 Plan expired in 2005 and thus no securities remain available for future issuance under that plan. Under the amended 2005 equity incentive plan, we have issued 1,482,669 shares to individuals as payment for services in the amount of $380,342 as allowed in the plan.

SELLING STOCKHOLDERS

The following table presents information as of April 9, 2009 and sets forth the number of shares of common stock beneficially owned by each of the Selling Stockholders. We are not able to estimate the amount of shares that will be held by each Selling Stockholder after the completion of this offering because: (1) the Selling Stockholders may sell less than all of the shares registered under this prospectus; (2) the Selling Stockholders may exercise less than all of their warrants; and (3) to our knowledge, the Selling Stockholders currently have no agreements, arrangements or understandings with respect to the sale of any of their shares. The following table assumes that all of the shares being registered pursuant to this prospectus will be sold. The Selling Stockholders are not making any representation that any shares covered by this prospectus will be offered for sale. Except as otherwise indicated, based on information provided to us by each Selling Stockholder, the Selling Stockholders have sole voting and investment power with respect to their shares of common stock. Except as otherwise noted, none of the Selling Stockholders 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 (2)	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
Biotex Pharma Investments, LLC (3)	40,000,000	24.3%	20,000,000	20,000,000	*
Revach Fund LP (4)	701,754	*	701,754	-	*
Omacatl Capital, LTD (5)	1,150,696	*	438,596	712,100	*
Richard Molinsky	400,000	*	400,000	-	*
Bernard and Miriam Pismeny JT TEN	1,055,000	*	200,000	855,000	*
Robin B. Lipinski	1,271,720	*	87,720	1,184,000	*
Sigma-Tau Pharmaceuticals, Inc. (6)	41,666,667	25.0%	16,666,667	25,000,000	15.0%
Mark Tolpin	269,789	*	269,789	-	*
Martin S. Kratchman	21,875	*	21,875	-	*
John Andreadis	21,875	*	21,875	-	*
Little Gem Life Sciences Fund LLC (7)	1,023,999	*	300,000	723,999	*
Prospera Technology, LLC (8)	1,000,000	*	1,000,000	-	*
George B. McDonald, M.D.	1,600,000	*	1,000,000	600,000	*
	50,000	*	50,000	-	*

Strategic Outsourcing Solutions, LLC (9)					
Numoda Corporation (10)	2,847,222	1.5%	3,333,334	347,222	*

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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 April 9, 2009, are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 167,070,944 shares of common stock outstanding as of April 9, 2009.

(1) The shares of common stock issuable upon the exercise of warrants are as follows: Biotex Pharma Investments, LLC - 20,000,000 shares; Revach Fund LP - 350,877 shares; Omacatl Capital, LTD - 219,298 shares; Richard Molinsky - 200,000 shares; Bernard and Miriam Pismeny, JT TEN - 100,000 shares; Robin B. Lipinski - 43,860 shares; Mark Tolpin - 100,000; Little Gem Life Sciences Fund, LLC - 300,000; Prospera Technology, LLC - 1,000,000; George B. McDonald - 1,000,000; and Strategic Outsourcing Solutions, LLC - 50,000. Includes 833,334 shares of our common stock that may be sold to Numoda Corporation pursuant to the terms of a Stock Purchase Agreement dated March 6, 2009 between the Company and Numoda Corporation.

(2) The shares of common stock issuable upon the exercise of warrants are as follows: Revach Fund LP - 350,877 shares; Omacatl Capital, LTD - 219,298 shares; Richard Molinsky - 200,000 shares; Bernard and Miriam Pismeny, JT TEN - 100,000 shares; Robin B. Lipinski - 43,860 shares; Mark Tolpin - 100,000; Little Gem Life Sciences Fund, LLC - 300,000; Prospera Technology, LLC - 1,000,000; George B. McDonald - 1,000,000; and Strategic Outsourcing Solutions, LLC - 50,000.

(3) Robert Kessler exercises voting or dispositive power with respect to the shares held of record by Biotex Pharma Investments, LLC.

(4) Chaim Davis exercises sole voting or dispositive power with respect to the shares held of record by Revach Fund LP.

(5) Baruch Ruttner exercises sole voting or dispositive power with respect to the shares held of record by Omacatl Capital, LTD.

(6) Gregg Lapointe, Paolo Cavazza and Claudio Cavazza exercise voting or dispositive power with respect to the shares held of record by Sigma-Tau Pharmaceuticals, Inc. The amount does not include 1,546,870 shares of common stock held by Paolo Cavazza.

(7) Jeffrey Benison exercises sole voting or dispositive power with respect to the shares held of record by Little Gem Life Sciences Fund, LLC.

(8) David Gentile exercises sole voting or dispositive power with respect to the shares held of record by Prospera Technology, LLC.

(9) Susan M. Little exercises sole voting or dispositive power with respect to the shares held of record by Strategic Outsourcing Solutions, LLC.

(10) Mary Schaheen exercises sole voting or dispositive power with respect to the shares held of record by Numoda Corporation.

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 $2,400,000 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 completion of the pivotal phase 3 clinical trial 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 operations.

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 SEC;
- 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 255,000,000 shares of capital stock, of which 250,000,000 shares are common stock, par value $0.001 per share, 4,600,000 shares are preferred stock, par value $0.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $0.05 per share, and 200,000 shares are Series C Convertible Preferred Stock, par value $0.05 per share. As of April 9, 2009, there were issued and outstanding 167,070,944 shares of common stock, options to purchase approximately 16,370,039 shares of common stock and warrants to purchase approximately 43,500,000 shares of common stock. The amount outstanding includes the 37,794,241 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 quoted on the Over-the-Counter Bulletin Board (“OTCBB”) under the symbol "DORB.” The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

	Price Range	
Period	High	Low
Fiscal Year Ended December 31, 2007:		
First Quarter	$0.71	$0.23
Second Quarter	$0.95	$0.20
Third Quarter	$0.40	$0.26
Fourth Quarter	$0.61	$0.15
Fiscal Year Ended December 31, 2008:		
First Quarter	$0.25	$0.16
Second Quarter	$0.19	$0.11
Third Quarter	$0.15	$0.09
Fourth Quarter	$0.12	$0.04

As of April 9, 2009, the last reported price of our common stock quoted on the OTCBB was $0.11 per share. The OTCBB price quoted reflects inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. We have approximately 1,075 registered holders of record.

Dividend Policy

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

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 Co