

DOR BIOPHARMA INC
Form S-1/A
April 14, 2009

As filed with the Securities and Exchange Commission on April 14, 2009.

Registration No.

333-157322

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DOR BioPharma, Inc.

(Name of registrant as specified in its charter)

Delaware (State or jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	41-1505029 (I.R.S. Employer Identification No.)
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DOR BioPharma, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200
(Address, including zip code, and telephone number, including area code,
of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
DOR BioPharma, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

with copies to:

Leslie J. Croland, Esq.
Edwards Angell Palmer & Dodge LLP
One North Clematis Street, Suite 400
West Palm Beach, Florida 33401-5552
(561) 833-7700

[Table of Contents](#)

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

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

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

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

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

Large accelerated filer Accelerated filer
 Non-accelerated filer Smaller reporting company
 (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee(2)
Common Stock, \$.001 par value per share	44,491,610	\$0.105	\$4,671,619	\$261

(1) Includes 20,914,035 shares of the Registrant's common stock, issued to certain Selling Stockholders, as defined in the accompanying prospectus, on January 20, 2009, 16,666,667 shares of the Registrant's common stock issued to one of the Selling Stockholders in connection with the execution of a letter of intent, 2,713,539 shares of the Registrant's common stock issued to certain Selling Stockholders as compensation for services rendered to the Registrant, up to 1,000,000 shares of the Registrant's common stock issuable upon exercise of warrants for a finder fee, up to 914,035 shares of the Registrant's common stock issuable upon exercise of warrants issued to certain selling stockholders on January 20, 2009, up to 1,450,000 shares of the Registrant's common stock issuable upon exercise of warrants for services rendered to the Registrant and up to 833,334 shares of the Registrant's common stock that may be issued to one of the Selling Stockholders as payment for services to be rendered to the Registrant. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), to the extent additional shares of Registrant's common stock may be issued or issuable as a result of a stock split, stock dividend

or other distribution declared at any time by the Registrant while this registration statement is in effect, this registration statement is hereby deemed to cover all such additional shares of common stock.

(2) Estimated solely for purposes of calculating the registration fee according to Rule 457(c) under the Securities Act on the basis of the average of the high and low prices of the Registrant's common stock quoted on the Over-the-Counter Bulletin Board on April 9, 2009. The Registrant previously paid \$211 in connection with the Registration Statement originally filed on February 13, 2009.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

[Table of Contents](#)

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

SUBJECT TO COMPLETION, DATED APRIL 14, 2009

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

The date of this prospectus is _____, 2009.

Description	Page
<u>Forward-Looking Statements</u>	<u>1</u>
<u>Prospectus Summary</u>	<u>2</u>
<u>Risk Factors</u>	<u>4</u>
<u>The Company</u>	<u>10</u>
<u>Management's Discussion and Analysis or Plan of Operation</u>	<u>23</u>
<u>Directors and Executive Officers</u>	<u>29</u>
<u>Executive Compensation</u>	<u>31</u>
<u>Security Ownership of Principal Stockholders and Management</u>	<u>34</u>
<u>Selling Stockholders</u>	<u>36</u>
<u>Use of Proceeds</u>	<u>37</u>
<u>Plan of Distribution</u>	<u>37</u>
<u>Description of Securities</u>	<u>38</u>
<u>Market for Common Equity and Related Stockholder Matters</u>	<u>39</u>
<u>Disclosure of Commission Position on Indemnification for Securities Act</u>	<u>40</u>
<u>Liabilities</u>	<u>40</u>
<u>Experts</u>	<u>40</u>
<u>Legal Matters</u>	<u>40</u>
<u>Index to Financial Statements</u>	<u>F-1</u>

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.

Table of Contents

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 statements include 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.

[Table of Contents](#)

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% royalty 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) reinstate development of our other biotherapeutics products, namely LPMTM Leuprolide;
- (g) continue to secure additional government funding for each of our biodefense programs, RiVax™ 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
Oraprine™	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 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.

[Table of Contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

7

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.

[table of contents](#)

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.

[Table of Contents](#)

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% royalty 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) reinstate development of our other biotherapeutics products, namely LPMTM Leuprolide;
- (g) continue to secure additional government funding for each of our biodefense programs, RiVax™ 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.

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 ("EMA"). 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 EMA. We reached this decision after consultation with the EMA 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.

[table of contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

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.

[table of contents](#)

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 RiVax™ 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 RiVax™. The grant was awarded to UTSW to further the development of RiVax™. We will not receive any monetary benefits from this grant; however, the successful completion of this work will enhance the value of our RiVax™ 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 RiVax™ 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.

[table of contents](#)

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-VACC™, both the A and the B antigens were capable of attaching to cells in the mucosal epithelium and inducing an immune response with similar magnitude to the injected vaccine. Our preclinical data 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-VACC™ 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.

[table of contents](#)

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.

Oraprime™

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. Oraprime™ 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 Oraprime™

The costs that we have incurred to develop Oraprime™ since 2000 total approximately \$400,000. Research and development costs for Oraprime™ 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.

[table of contents](#)

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
Oraprine™	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

[table of contents](#)

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 IND includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

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

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

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

In the 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 RiVax™ 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.

[table of contents](#)

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 Oraprine™ 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 Remicade™ for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®. Entocort® is structurally similar to beclomethasone dipropionate, and the FDA approved Entocort for Crohn's disease late in 2001. In 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, Inkind 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.

[table of contents](#)

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.

[Table of Contents](#)

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) reinstate development of our other biotherapeutics products, namely LPMTM Leuprolide;
- (g) continue to secure additional government funding for each of our biodefense programs, RiVax™ 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 RiVax™ 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.

[table of contents](#)

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 an