DOR BIOPHARMA INC
Form 424B3
March 26, 2007

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Registration No. 333-133975

PROSPECTUS

DOR BioPharma, Inc.

26,341,261 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 26,341,261 shares of our common stock by the selling stockholders named in this prospectus in the section "Selling Stockholders," including their pledgees, assignees and successors-in-interest, whom we collectively refer to in this document as the "Selling Stockholders." We completed a stock purchase transaction pursuant to which we issued to certain of the Selling Stockholders an aggregate of 13,099,964 shares of our common stock and warrants to purchase up to an aggregate of 13,099,964 shares of common stock (the "Purchased Warrants"). In connection with the stock purchase transaction, we issued to two of the Selling Stockholders, as a broker's fee, cash in the amount of $192,750 and warrants to purchase up to an aggregate of 1,361,708 shares of our common stock (together with the Purchased Warrants, the "Warrants"). In addition, we issued 3,068,183 shares of our common stock to certain Selling Shareholders who received the shares as a result of a merger of one of our subsidiaries. The common stock offered by this prospectus shall be adjusted to cover any additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions. The prices at which the Selling Stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of any of the shares covered by this prospectus. References in this prospectus to the "Company," "we," "our," and "us" refer to DOR BioPharma, Inc.

Our common stock is quoted on the Over-the-Counter Bulletin Board ("OTCBB") under the symbol "DORB.OB." On March 7, 2007, the last reported sale price for our common stock as reported on the OTCBB was $0.57 per share.

Investing in our common stock involves certain risks. See "Risk Factors" beginning on page 5 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.
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Miami, Florida 33131
(305) 534-3383

The date of this prospectus is March 20, 2007

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

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

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

FORWARD-LOOKING STATEMENTS

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

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

- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to make certain that our cash expenditures do not exceed projected levels;
- our ability to obtain future financing or funds when needed;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- our ability to successfully obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;
- our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;
- our ability to patent, register and protect our technology from challenge and our products from competition;
- maintenance or expansion of our license agreements with our current licensors;
- maintenance of a successful business strategy;
- the FDA not considering orBec® approvable based upon existing studies because orBec® did not achieve statistical significance in its primary endpoint in the pivotal Phase III clinical study (i.e. a p-value of less than or equal to 0.05);
- orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, if required, or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- we are dependent on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;
- orBec® may not gain market acceptance; and
- others may develop technologies or products superior to our products.

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

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

PROSPECTUS SUMMARY

The Company

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

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

Our principal executive offices are located at 1101 Brickell Avenue, Suite 701-S, Miami, Florida 33131 and our telephone number is 786-425-3848.

orBec®

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

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

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

RiVax™

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

BT-VACC™

Our botulinum toxin vaccine, called BT-VACC™, was developed through the research of Dr. Lance Simpson at Thomas Jefferson University in Philadelphia, Pennsylvania. Botulinum toxin is the product of the bacteria *Clostridium botulinum*. Botulinum toxin is one of the most poisonous natural substances known. Botulinum toxin causes acute, symmetric, descending flaccid paralysis due to its action on peripheral cholinergic nerves. Paralysis typically presents 12 to 72 hours after exposure. Death results from paralysis of the respiratory muscles. Current treatments include respiratory support and passive immunization with antibodies which must be administered before symptoms occur, which leaves little time post-exposure for effective treatment.

Recent Developments

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

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

released us from the exclusivity period we have retained RBC Capital Markets Corporation ("RBC") to provide certain investment banking and financial advisory services in connection with this transaction and other possible acquisition and licensing transactions.

On February 9, 2007, we completed the sale of an aggregate of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for an aggregate purchase price of $5,490,000. Pursuant to a registration rights agreement, we agreed to file this registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

As of March 1, 2007, there were 88,701,291 shares outstanding, including the 16,168,147 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus, including the 10,173,114 shares of our common stock underlying warratns, represent approximately 28% of the total common stock outstanding as of March 1, 2007, assuming such Warrants were fully exercised.

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

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

Risk Factors

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

Risks Related to our industry

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

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

All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through December 31, 2006, we had expended approximately $17,400,000 developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $6.0 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our leading product candidate, or another one of our product candidates, we may require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various

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

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

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

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

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

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

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

placebo. Additional clinical trials may be necessary prior to approval by the FDA of a marketing application.

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

There may be unforeseen challenges in developing biodefense products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have only eight employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Dr. Christopher J. Schaber, Chief Executive Officer, was hired in August 2006; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was on the Board for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. We will not be successful if this management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation

on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

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

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

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

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

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

Shareholders may suffer substantial dilution.

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

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

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

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

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

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

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

RECENT DEVELOPMENTS

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

payment is made.

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

On February 9, 2007, we completed the sale of an aggregate of 11,680,850 shares of our common stock to institutional investors and certain of our officers and directors for an aggregate purchase price of $5,490,000. Pursuant to a registration rights agreement, we agreed to file this registration statement with the Securities and Exchange Commission in order to register the resale of the shares.

BUSINESS

Overview

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

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

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

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Sigma-Tau until March 1, 2007 we did not have any discussions with them regarding this proposal. Since Sigma-Tau released us from the exclusivity period we have retained RBC Capital Markets Corporation ("RBC") to provide certain investment banking and financial advisory services in connection with this transaction and other possible acquisition and licensing transactions.

BioTherapeutics Overview

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

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

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

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

BioDefense Overview

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

the Project Bioshield Act of 2004, which provides incentives to industry to supply biodefense countermeasures to the Strategic National Stockpile.

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

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

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

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

BioTherapeutics Division

orBec®

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

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

Comprehensive Long-Term Mortality Results

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

200 Days Post Transplant Mortality Results

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

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

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

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

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

Safety and Adverse Events

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

Commercialization and Market

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

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

On January 3, 2007, we received $3 million under a non-binding letter of intent with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), which granted Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business

transaction or strategic alliance regarding orBec® and potentially other DOR pipeline compounds until March 1, 2007. Sigma-Tau is a pharmaceutical company that creates novel therapies for the unmet needs of patients with rare diseases. They have both prescription and consumer products in metablolic, oncology, renal and supplements.

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

Research and Development

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

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

About Graft-versus-Host Disease

Graft-versus-Host Disease occurs in patients following an allogeneic bone marrow transplant in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes in the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50 to 70% of the approximate 12,000 annual allogeneic transplant patients in the United States will develop some form of acute GI GVHD.

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

relapse, as well as substantial rates of mortality due to opportunistic infection.

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

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

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

Future Potential Indications of orBec®

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

Other Products in BioTherapeutics Pipeline

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

LPM™ - Leuprolide

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

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

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

Research and Development

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

Cost and Development analysis for LPM™ Leuprolide

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