DOR BIOPHARMA INC
Form S-1
February 13, 2009

As filed with the Securities and Exchange Commission on February 13, 2009.

Registration No.

333-_____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DOR BioPharma, Inc.

(Name of registrant as specified in its charter)

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

DOR BioPharma, Inc.
850 Bear Tavern Road, Suite 201
Ewing, New Jersey 08628
(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.
850 Bear Tavern Road, Suite 201
Ewing, New Jersey 08628
(609) 538-8200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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with copies to:
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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: ý

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 ý
(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	41,158,276	$0.13	$5,350,576	$211

(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, 213,539 shares of the Registrant's common stock issued to certain Selling Stockholders on December 1, 2008 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, and up to 1,450,000 shares of the Registrant's common stock issuable upon exercise of warrants for services 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 February 9, 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

I

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 FEBRUARY 13, 2009

PROSPECTUS

DOR BioPharma, Inc.

41,158,276 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 41,158,276 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 213,539 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. 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 February 9, 2009, the last reported sale price for our common stock as quoted on the OTCBB was $0.12 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.
850 Bear Tavern Road, Suite 201
Ewing, New Jersey 08628
(609) 538-8200

Table of Contents

II

The date of this prospectus is _____, 2009.

Description	Page
Forward-Looking Statements	1
Prospectus Summary	2
Risk Factors	3
The Company	13
Management's Discussion and Analysis or Plan of Operation	30
Directors and Executive Officers	40
Executive Compensation	41
Security Ownership of Principal Stockholders and Management	45
Selling Stockholders	47
Use of Proceeds	48
Plan of Distribution	48
Description of Securities	49
Market for Common Equity and Related Stockholder Matters	50
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	51
Experts	51
Legal Matters	51
Index to Financial Statements	F-1

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

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

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

FORWARD-LOOKING STATEMENTS

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

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

- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to make certain that our cash expenditures do not exceed projected levels;
- our ability to obtain future financing or funds when needed;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- our ability to successfully obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;
- our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;
- our ability to patent, register and protect our technology from challenge and our products from competition;
- maintenance or expansion of our license agreements with our current licensors;
- maintenance of a successful business strategy;
- our ability to execute and successfully complete the upcoming confirmatory Phase 3 clinical trial of orBec® for the treatment of gastrointestinal Graft-versus-Host disease (“GI GVHD”);
- the possibility that orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- our dependence on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;
- the possibility that orBec® may not gain market acceptance; and
- that others may develop technologies or products superior to our products.

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

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

PROSPECTUS SUMMARY

About Our Company

We are a late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. We 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 acute GI GVHD;
(b) make orBec® available worldwide through named patient access programs for the treatment of GI GVHD;
(c) 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 United States, Canada and Mexico, Sigma-Tau will pay us a 35% roylaty on net sales;
(d) conduct a Phase 2 clinical trial of orBec® for the prevention of GI GVHD;
(e) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as radiation enteritis, radiation injury and Crohn's disease;
(f) reinitiate development and manufacturing of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area;
(i) explore business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company; and
(j) acquire or in-license new clinical-stage compounds for 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 to be initiated in 2009
Oral BDP	Radiation Enteritis and Radiation Exposure	Phase ½ trial to be initiated in 2009
LPMTM – Leuprolide	Endometriosis and Prostate Cancer	Phase 1 trial to be initiated in 2009

Biodefense Products

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

We have stated in our footnotes to the consolidated financial statements as of the period ended September 30, 2008, and reported in our quarterly report for the same period, that we will continue as a going concern and that our ability to continue our operations is dependent on our ability to raise sufficient capital. Since our quarterly report for the period ended September 30, 2008, we have raised an additional $8,384,200 through equity financings. We believe that this funding will allow us to continue operations through mid year 2010.

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

The Offering

This prospectus relates to the offer and sale, from time to time, of up 41,158,276 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 February 11, 2009, there were 164,524,739 shares outstanding, including 37,794,241 of the 41,158,276 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus represents approximately 25.02% of the total common stock outstanding as of February 11, 2009.

RISK FACTORS

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

Risks Related to our Industry

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

We have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2008, we had $686,216 in cash available. Since September 30, 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 for a sum of $8,384,200. Based on our projected budgetary needs over the next 18 months, we expect to be able to maintain the current level of our operations through mid year 2010 and begin the pivotal Phase 3 confirmatory clinical trial of orBec® for the treatment of acute gastrointestinal 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. We estimate that the overhead revenue contribution from our existing NIH biodefense grants will generate an additional $650,000 over the next four quarters.

All of our products are currently in preclinical studies or clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. Through September 30, 2008, we had expended approximately $23,600,000 developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $7 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, 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. 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:

Table of Contents

4

- 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

- 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.

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

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

On October 18, 2007, we received a not approvable letter from the FDA for our lead product candidate, orBec®, for the treatment of 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 (“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 GI GVHD in the first 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.

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

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

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

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 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.

Table of Contents

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

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

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

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

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

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

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

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of

these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

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

We currently rely on license agreements from the University of Texas Southwestern Medical Center, the University of Texas Medical Branch at Galveston, Thomas Jefferson University, and George B. McDonald 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 collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

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

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

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

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

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

able to compete successfully with our existing and future competitors.

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 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 seven employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Dr. Christopher J. Schaber, our Chief Executive Officer, was hired in August 2006; Evan Myrianthopoulos, our Chief Financial Officer, was hired in November 2004, although he was a member of our Board of Directors for two years prior to that; James Clavijo, our Controller, Treasurer and Corporate Secretary was hired in October 2004; and Dr. Robert Brey, our Chief Scientific Officer was hired in 1996. In August 2006, Dr. James S. Kuo was appointed Chairman of the Board. In June 2007, Cyrille F. Buhrman 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.

Risks Related to our Common Stock

Our stock price is highly volatile.

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

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

In addition, potential dilutive effects of future sales of shares of common stock by 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 December 31, 2008 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 February 9, 2009, our common stock traded at $0.12. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

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

On April 18, 2006, our stock was delisted from the American Stock Exchange (“AMEX”) and began trading on the 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.

Table of Contents

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 16,730,039 shares of our common stock of a current weighted average exercise price of approximately $0.24.

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 in an aggregate amount of $8.5 million from time to time over a 25 month period. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale.

We already have sold 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 may 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 February 9, 2009, the 18.8 million shares would have represented approximately 13.5% 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 may be terminated in the event of a default under the agreement. In addition, we may not require Fusion Capital to purchase any shares of our common stock if the purchase price is less than $0.10 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. The closing price of our common stock on February 9, 2009, was $0.12.

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

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

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

THE COMPANY

RECENT DEVELOPMENTS

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. They have both prescription and consumer products in metabolic, oncology, renal and supplements. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of our common stock at the market price of $0.09 per share, representing 16,666,667 shares.

On February 12, 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 United States, 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, a $1 million payment, will be made upon the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of GI GVHD, which is expected to occur in the first 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 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. As part of the transaction, the Company granted Sigma-Tau certain demand and piggy-back registration rights.

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

BUSINESS OVERVIEW

We are a late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. We 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 acute GI GVHD;
(b) make orBec® available worldwide through named patient access programs for the treatment of GI GVHD;
(c) 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 United States, Canada and Mexico, Sigma-Tau will pay us a 35% roylaty on net sales;

(d) conduct a Phase 2 clinical trial of orBec® for the prevention of GI GVHD;
(e) evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as radiation enteritis, radiation injury and Crohn's disease;
(f) reinitiate development and manufacturing of our other biotherapeutics products, namely LPMTM Leuprolide;
(g) continue to secure additional government funding for each of our biodefense programs, RiVaxTM and BT-VACCTM, through grants, contracts and procurements;
(h) convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area;
(i) explore business development and acquisition strategies under which we may be considered to be an attractive acquisition candidate by another company; and
(j) acquire or in-license new clinical-stage compounds for development.

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

orBec®

On January 5, 2009, we announced that 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 ("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).

Our lead product, orBec®, has been evaluated in a randomized, multi-center, double-blind, placebo-controlled pivotal Phase 3 clinical trial for the treatment of GI GVHD, a serious and life-threatening gastrointestinal inflammation associated with allogeneic hematopoietic cell transplantation ("HCT"). While orBec® did not achieve statistical significance in time to treatment failure through Day 50 (p-value 0.1177), the primary endpoint of its pivotal Phase 3 trial, there was a positive trend observed and it did achieve statistical significance in other key outcomes such as median time to treatment failure through Day 80 (p-value 0.0226) and treatment failure rate at Day 80 (p-value 0.005). Most importantly, orBec® demonstrated a statistically significant survival advantage in comparison to placebo at 200 days post-transplantation (p-value 0.0139) and at one year post-randomization (p-value 0.04).

Table of Contents

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® (oral beclomethasone dipropionate) with the U.S. Food and Drug Administration ("FDA") for the treatment of GI GVHD. On November 3, 2006, we also filed a Marketing Authorization Application ("MAA") for orBec® with the European Central Authority, European Medicines Evaluation Agency ("EMEA"). On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® (oral beclomethasone dipropionate) for the treatment of GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an "End of Review Conference" with the FDA to further understand the letter and gain clarity as to the next steps. On December 7, 2007, we announced 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, such as potentially enrolling patients that would not be eligible for the Phase 3 study.

In May 2008, we voluntarily withdrew the MAA that was being reviewed by EMEA. We reached this decision after consultation with the EMEA and determining that confirmatory evidence of clinical efficacy will be required for approval. This is consistent with the request made by the FDA. The withdrawal of an MAA application does not prejudice the possibility of making a new application at a later stage.

On June 30, 2008, we announced that we 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 will be also able to take full advantage of early reporting of results to potential licensing partners and others. In order to execute the collaboration, we will require further funding from financings or partnerships.

On December 1, 2008, we received $1.5 million under a letter of intent with Sigma-Tau, which grants Sigma-Tau an exclusive right to negotiate terms and conditions for a possible business transaction or strategic alliance regarding orBec® and potentially other pipeline compounds until March 1, 2009. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of our common stock at the market price of $0.09 per share, which will be considered an advance payment to be deducted from upfront monies due to us by Sigma-Tau pursuant to the collaboration and supply agreement between the two parties.

On November 25, 2008, we announced that the Therapeutics Goods Administration of Australia has 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 Named Patient Access Program ("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 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 GI GVHD after allogeneic HCT with myeloablative conditioning regimens. The trial is being conducted by Paul Martin, M.D., at the FHCRC in Seattle, Washington and is being supported, in large part, by an NIH grant. We will not receive any 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.

orBec® Comprehensive Long-Term Mortality Results

Among the data reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, orBec® showed continued survival benefit when compared to placebo one year after randomization in the pivotal Phase 3 clinical trial. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo

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

Table of Contents

200 Days Post Transplantation Mortality Results

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

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

In 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).” Although orBec® did not achieve statistical significance in the primary endpoint of its Phase 3 trial, namely time to treatment failure through Day 50 (p=0.1177), orBec® did achieve statistical significance in other key outcomes such as reduction in the risk of treatment failure through Day 80 (p=0.0226) and, most importantly, demonstrated a statistically significant long-term survival advantage compared with placebo. The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

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.

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.

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of 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 United States, 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 GI GVHD, which is expected to occur in the first 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.

Research and Development Analysis for orBec®

Since 2000, we have incurred expenses of approximately $15,900,000 in the development of orBec®. Research and development costs for orBec® totaled $884,341 for the nine months ended September 30, 2008 and $2,288,615 and $3,060,778 for the years ended December 31, 2007 and 2006, respectively.

About Graft-versus-Host Disease

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

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

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

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

Table of Contents

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

Future Potential Indications of orBec® and Oral BDP

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

DOR 201

On December 8, 2008, we announced that the FDA has completed its review and cleared the Investigational New Drug Application ("INDA") 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. 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 United States 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.

Table of Contents

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. 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 United States annually who receive abdominal or pelvic external beam radiation treatment for cancer who are at risk of developing acute and chronic radiation enteritis.

BioDefense

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 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 at Dallas, DOR's academic partner on the RiVax™ program. 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 government’s two animal rule.

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

Table of Contents

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.

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

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.

Research and Development Analysis for RiVax™

The costs that we have incurred to develop RiVax™ since 2002 total approximately $6,850,000. Research and development costs for RiVax™ totaled $249,318 for the nine months ended September 30, 2008 and $1,350,364 and $2,235,709 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 $1,961,074 were for costs reimbursed under the NIH grant, repsectively.

BT-VACC™

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

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

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

Table of Contents

Research and Development Analysis for BT-VACC™

The costs that we have incurred to develop BT-VACC™ from 2002 total approximately $2,250,000. Research and development costs for BT-VACC™ totaled $154,795 for the nine months ended September 30, 2008 and $360,997 and $294,405 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

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 the proper 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.

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. This Phase 1 study will require further funding from financings or partnerships.

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 $111,387 for the nine months ended September 30, 2008 and $38,254 and $5,679 for the years ended December 31, 2007 and 2006, respectively. These costs are mainly legal costs in connection with maintenance of our patent positions and for preclinical formulation work.

OraprineTM

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

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

Research and Development Analysis for OraprineTM

The costs that we have incurred to develop Oraprine™ since 2000 total approximately $400,000. Research and development costs for Oraprine™ totaled $4,000 for the nine months ended September 30, 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.

LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs

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

enhancer for lipophilic compounds. The polymers used in these formulations can either be commercially available or proprietary polymerized lipids and lipid analogs. This program is suspended pending further funding from financing or partnerships.

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 to be initiated in 2009
Oral BDP	Radiation Enteritis and Radiation Exposure	Phase 1/2 trial to be initiated in 2009
LPMTM – Leuprolide	Endometriosis and Prostate Cancer	Phase 1 trial to be initiated in 2009
OraprineTM	Oral lesions resulting from GVHD	Phase 1/2 trial suspended
LPETM and PLPTM Systems	Delivery of Water-Insoluble Drugs	Pre-Clinical

Biodefense Products

Select Agent	Currently Available Countermeasure	DOR Biodefense Product
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable Ricin Vaccine Phase 1 Clinical Trial Successfully Completed
Botulinum Toxin	No vaccine or antidote currently FDA approved	Second Phase 1 trial enrolling 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 United States and other countries. All products must go through a series of tests, including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary to protect the safety of subjects.

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

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

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

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

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

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

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

Marketing Strategies

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

We are actively seeking a partner for the development of other potential indications of orBec® as well as for our OraprineTM, LPMTM – Leuprolide, LPETM and PLPTM systems for delivery of water-insoluble drugs.

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

Competition

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

Biodefense Vaccine Competition

We face intense competition in the area of biodefense from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Dynavax, Emergent Biosolutions (formerly Bioport Corporation), VaxGen, Inc., Chimerix, Inc., Human Genome Sciences, Inc., Coley Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmathene, SIGA Pharmaceuticals and others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. For example, Avecia Biotechnology, Inc. has received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen received an approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of

Anthrax vaccine. This contract was rescinded in January 2007 by the HHS because of the inability of Vaxgen to enter into Phase 2 clinical trials according to contract timelines. Several companies have received development grants from NIH for biodefense products. For example, Coley Pharmaceuticals, Inc. has received a $6 million Department of Defense grant to develop vaccine enhancement technology. Dynport Vaccine Company, LLC, a prime contractor with the DOD, currently has a $200 million contract to develop vaccines for the U.S. Military, including a multivalent botulinum toxin vaccine. Although we have received significant grant funding to date for product development, we have not yet been obtained contract awards for government procurement of products.

Table of Contents

orBec® Competition

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

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

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

Patents and Other Proprietary Rights

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

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

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

Under the Waxman-Hatch Act, a patent which claims a product, use or method of manufacture covering drugs and certain other products may be extended for up to five years to compensate the patent holder for a portion of the time required for development and FDA review of the product. The Waxman-Hatch Act also establishes periods of market exclusivity, which are periods of time ranging from three to five years following approval of a drug during which the FDA may not approve, or in certain cases even accept, applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and efficacy data.

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 $40,000 per annum as a consultant.

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

Ricin Vaccine Intellectual Property

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

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

Botulinum Toxin Vaccine Intellectual Property

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

Table of Contents

28

Description of Property

We currently lease approximately 2,500 square feet of office space at 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628. The office space currently serves as our corporate headquarters. We pay rent of approximately $5,800 per month, or $28 per square foot, on a month-to-month lease, which was entered into on October 1, 2008. We anticipate that we will seek a new facility in the second quarter of 2009.

Employees

As of December 31, 2008, we had seven full-time employees, three of whom are Ph.D.s.

Research and Development Spending

We spent approximately $900,000 in the nine months ended September 30, 2008 and $3,100,000 and $4,800,000 in the years ended December 31, 2007 and 2006, respectively, on research and development.

Legal Proceedings

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes 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 late-stage research and development biopharmaceutical company focused on the development of oral therapeutic products intended for areas of unmet medical need and biodefense vaccines. We were incorporated in Delaware in 1987.

Our business strategy is to:

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

Critical Accounting Policies

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

Table of Contents

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

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

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

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

We capitalized $190,801 and $356,192 in patent related costs during the nine months ended September 30, 2008 and the year ended December 31, 2007, respectvely. These amounts are represented in the cash flow statements, in the section for investing activities presented in the financial statements. On the balance sheet as of September 30, 2008 and December 31, 2007, these amounts are presented on the line intangible assets, net in the amount of $1,412,278 and $1,320,787, respectively.

Research and Development Costs

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

Revenue Recognition

Our revenues are generated from U.S. government grants and from Orphan Australia for 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.

Material Changes in Results of Operations

Three and Nine Months Ended September 30, 2008 Compared to Three and Nine Months Ended September 30, 2007.

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

For the three months ended September 30, 2008, we had a net loss of $475,701 as compared to a net loss of $1,246,982 for the three months ended September 30, 2007, for a decrease of $771,281, or 62%. For the nine months ended September 30, 2008, we had a $3,103,579 net loss as compared to $4,966,848 in the nine months ended September 30, 2007, for a decrease of $1,863,269, or 38%. This decrease is primarily attributed to lower research and development costs and lower costs associated with preparation of FDA and European regulatory matters as well as a reduction in general and administrative expenses, such as, public and investor relation expenses, a reduction in employee, travel and consultant expenses, lower expenses taken for stock based compensation in the amount of $300,185, and the dilution expense taken for stock issued to investors from the April 2006 private placement in the amount of $308,743 in 2007.

For the three months ended September 30, 2008, we had revenues of $605,736 as compared to $429,445 in the three months ended September 30, 2007, for an increase of $176,291, or 41%. For the nine months ended September 30, 2008, we had grant revenues of $1,771,620 as compared to $943,737 in the nine months ended September 30, 2007, for an increase of $827,883, or 88%. During 2008 we achieved certain R&D milestones with our subcontractors and made drawdowns from our NIH grants. In addition, we had revenue of $40,618 from Orphan Australia for NPAP sales of orBec®. We also incurred expenses related to that revenue in the three months ended September 30, 2008 and 2007 of $538,182 and $301,672, respectively, for an increase of $236,510, or 78%. For the nine months ended September 30, 2008 and 2007, we incurred expenses to that revenue of $1,459,206 and $669,882 respectively. Of the difference, $182,600 is due to a reclassification of expenses from research and development costs to cost of sales. Costs of revenues for the grants relate to payments made to subcontractors and universities in connection with the grants. Costs of goods associated with NPAP sales of orBec® were $10,551. We also recorded a $100,000 allowance as a reserve for our orBec® inventory.

Our gross profit for the three months ended September 30, 2008 was $67,554 as compared to $127,773 in the three months ended September 30, 2007, for a decrease of $60,219, or 47%. For the nine months ended September 30, 2008, we had a gross profit of $312,414 as compared to $273,855 in the nine months ended September 30, 2007, for an increase of $38,559, or 14%. A portion of this difference relates to the aforementioned reclassification error. In the third quarter of 2008, we also capitalized inventory in the net amount of $147,545 and $60,311 for certain orBec® costs that were expensed as research and development expenses in 2008 and 2007, respectively, and recorded a $100,000 allowance as a reserve for our orBec® inventory.

Research and development spending decreased by $531,430, or 90%, to $60,238, for the three months ended September 30, 2008 as compared to $591,668 for the corresponding period ended September 30, 2007. A portion of this decrease is due to the reclassification of research and development expenses to inventory. For the nine months ended September 30, 2008, we had $1,403,841 of research and development spending as compared to $2,611,220 in the nine months ended September 30, 2007, for a decrease of $1,207,379, or 46%. During 2008, we incurred expenses for FDA and European regulatory matters, for clinical preparation of orBec® and LPM formulation work. The majority of research and development expenses in 2007 were related to FDA and European regulatory matters.

General and administrative expenses decreased $98,797, or 19%, to $410,336 for the three months ended September 30, 2008, as compared to $509,133 for the corresponding period ended September 30, 2007. For the nine months ended September 30, 2008, we had general and administrative expenses of $1,812,972 as compared to $2,243,212 in the nine months ended September 30, 2007, for a decrease of $430,240, or 19%. The decrease was primarily due to the dilution expense taken in the first quarter of 2007 for stock issued to investors in the April 2006 private placement in the amount of $308,743. Additionally, the decrease was due to a reduction in employee and consultant expenses, travel expenses and expenses for public and investor relations of approximately $230,000. During the first quarter of 2008, commitment shares were issued and an expense of $270,000 was recorded as a result of the Fusion Capital equity transaction.

Stock based compensation expenses for research and development decreased $37,778, or 49%, to $39,584 for the three months ended September 30, 2008, as compared to $77,362 for the corresponding period ended September 30,

2007. For the nine months ended September 30, 2008, we had $118,750 in stock based compensation expenses for research and development as compared to $164,890 in the nine months ended September 30, 2007, for a decrease of $46,140 or 28%.

Table of Contents

Stock based compensation expenses for general and administrative decreased $169,921, or 82%, to $36,792 for the three months ended September 30, 2008, as compared to $206,713 for the corresponding period ended September 30, 2007. For the nine months ended September 30, 2008, we had $110,378 in stock based compensation expenses for general and administrative as compared to $364,423 in the nine months ended September 30, 2007, for a decrease of $254,045, or 70%.

Interest income for the three months ended September 30, 2008 was $5,391 as compared to $10,121 for the three months ended September 30, 2007, representing a decrease of $4,730, or 47%. For the nine months ended September 30, 2008, we had $32,248 of interest income as compared to $144,062 in the nine months ended September 30, 2007, for a decrease of $111,814, or 78%. This decrease is due to lower cash balances in 2008 as compared to 2007.

Interest expense for the three months ended September 30, 2008 was $1,696 as compared to $0 for the three months ended September 30, 2007. For the nine months ended September 30, 2008, we had $2,300 of interest expense as compared to $1,020 in the nine months ended September 30, 2007, for an increase of $1,280, or 125%. This increase was the result of higher balances that were short-term financed for insurance premiums due.

Financial Condition

Cash and Working Capital

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. As of September 30, 2008, we had cash of $686,216 as compared to $2,220,128 as of December 31, 2007. As of November 3, 2008, we had cash of approximately $520,000. As of September 30, 2008, we had working capital deficit of $537,997 as compared to working capital of $1,243,638 as of December 31, 2007, representing a decrease of $1,781,635. For the nine months ended September 30, 2008, our cash used in operating activities was approximately $2,100,000, compared to $5,200,000 for the corresponding period ended September 30, 2007.

Management's plan is as follows:

- We have and will utilize Named Patient Sales wherever possible in countries outside the United States to generate revenues from orBec®.
- We are exploring outlicensing opportunities for LPM-Leuprolide and BioDefense programs in the United States and in Europe.

If we obtain additional funds through the issuance of equity or equity-linked securities, shareholders may experience significant dilution and these equity securities may have rights, preferences or privileges senior to those of our common stock. The terms of any debt financing may contain restrictive covenants which may limit our ability to pursue certain courses of action. We may not be able to obtain such financing on acceptable terms if at all. If we are unable to obtain such financing when needed, or to do so on acceptable terms, we may be unable to develop our products, take advantage of business opportunities, respond to competitive pressures or continue our operations.

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

Since September 30, 2008, we have issued a total of 62,580,702 shares of common stock and warrants to purchase 20,914,035 shares of common stock for a sum of $8,384,200.

Expenditures

Under our austerity budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our expenditures for the next 12 months to be approximately $1,200,000, not inclusive of BioDefense programs, or programs covered under existing NIH or orphan grants, and not including a new confirmatory Phase 3 clinical trial for orBec® for the treatment of GI GVHD. In order to fund a portion of these expenditures we will need funding from financings and partnerships. We anticipate grant revenues in the next 12 months to offset research and development expenses for the development of our ricin toxin vaccine and botulinum toxin vaccine in the amount of approximately $2,100,000, with $600,000 contributing towards our overhead expenses.

The table below details our costs by program for the nine months ended September 30:

	2008	2007
Program - Research & Development Expenses		
orBec®	$ 884,341	$ 1,999,562
RiVax™	249,318	317,390

BT-VACC™	154,795	256,914
Oraprine™	4,000	5,100
LPMTM-Leuprolide	111,387	32,254
Research & Development Expense	$ 1,403,841	$ 2,611,220
Program – Cost of Goods Sold and Reimbursed under Grants		
orBec®	$ 10,551	$ -
RiVax™	1,266,049	636,979
BT-VACC™	82,606	32,903
Cost of Goods Sold and Reimbursed under Grant	$ 1,359,206	$ 669,882
TOTAL	$ 2,863,047	$ 3,281,102

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

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

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

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

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

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

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

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

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

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

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

Interest expense for the twelve months ended December 31, 2007 was $1,020 as compared to $5,308 for the twelve months ended December 31, 2006, a decrease of $4,288 or 81%. This decrease was the result of lower balances that were short-term financed for insurance premiums due and therefore less interest was accrued and paid.

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

Financial Condition

Cash and Working Capital

As of December 31, 2007, we had cash of $2,220,128 as compared to $119,636 as of December 31, 2006. As of March 24, 2008 we had cash of approximately $2,000,000. As of December 31, 2007, we had working capital of $1,243,638 as compared to negative working capital of $2,211,387 as of December 31, 2006, representing an increase of $3,455,025. For the twelve months ended December 31, 2007, our cash used in operating activities was approximately $6,000,000, compared to $4,100,000 for the corresponding period ended December 31, 2006.

Based on the our current rate of cash outflows, cash in the bank, we believe that our cash will be sufficient to meet its anticipated cash needs for working capital and capital expenditures through mid year 2010.

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

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

Expenditures

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

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

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

Leases

The following summarizes our contractual obligations at September 30, 2008, and the effect those obligations are expected to have on our liquidity and cash flow in future periods.

Contractual Obligation	Year 2008	Year 2009	Year 2010
Non-cancelable obligation (1)(2)	$ 7,000	$ 4,500	4,500
TOTALS	$ 7,000	$ 4,500	$ 4,500

(1) On October 1, 2008, we signed a month to month lease to occupy office space in Ewing, New Jersey.

(2) On April 24, 2008, we signed a three year lease for a copier.

Equity Transactions

On February 11, 2009, 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 January 20, 2009, we received $2,384,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreement, we sold 20,914,035 common shares together with five year warrants to purchase up to 20,914,035 shares of our common stock at $0.14 per share. The expiration date of the warrants will be accelerated if the Company's common stock meets certain price thresholds and we would receive additional gross proceeds of approximately $2.9 million if exercised.

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. Under the terms of the letter of intent, Sigma-Tau purchased $1.5 million of our common stock at the market price of $0.09 per share, representing 16,666,667 shares.

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

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

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

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

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

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

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements.

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the fiscal year ended December 31, 2007 or the quarter ended September 30, 2008.

Table of Contents

DIRECTORS AND EXECUTIVE OFFICERS

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

Name	Age	Position
James S. Kuo, M.D., M.B.A.	45	Chairman of the Board
Cyrille F. Buhrman	36	Director
Christopher J. Schaber, Ph.D.	42	Chief Executive Officer, President, and Director
Evan Myrianthopoulos	44	Chief Financial Officer, and Director
James Clavijo, C.P.A., M.A.	43	Controller, Treasurer, and Corporate Secretary

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

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

Christopher J. Schaber, Ph.D., has been our President and Chief Executive Officer and a director since August 2006. Dr. Schaber also currently serves on the boards of both the Alliance for BioSecurity and BioNJ, Inc. Prior to joining

DOR, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, preclinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising in excess of $150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. from Western Maryland College, his M.S. in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. in Pharmaceutical Sciences from The Union Graduate School.

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

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

EXECUTIVE COMPENSATION

Summary Compensation

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

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber (1)	CEO & President	2007	$300,000	$100,000	$155,409	$47,798	$603,207
		2008	$300,000	$100,000	$185,721	$24,844	$610,565
Evan Myrianthopoulos (2)	CFO	2007	$200,000	$ 50,000	$146,938	$44,786	$441,724
		2008	$200,000	$ 50,000	$ 66,033	$23,474	$339,507
James Clavijo (3)	Controller, Treasurer & Secretary	2007	$155,000	$ 35,000	$ 53,115	$13,191	$243,115
		2008	$155,000	$ 35,000	$ 34,226	$14,991	$239,217

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

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

(3) Mr. Clavijo deferred payment of his 2008 annual bonus of $35,000. Option Awards include the value of stock option awards of vested shares of common stock as required by FASB No. 123R. Other Compensation for 2008 includes $14,991 for insurance costs. Other Compensation for 2007 includes $13,191 for insurance costs

Potential Issuance of Shares

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

Table of Contents

41

Employment and Severance Agreements

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

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

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

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

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

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

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

Mr. Clavijo's monetary compensation (base salary of $155,000 and bonus of $35,000) remained unchanged from 2006. He will be paid six months severance (subject to set off) upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Clavijo's options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the rest of their term and become property of Mr. Clavijo's immediate family.

Table of Contents

Outstanding Equity Awards at Fiscal Year-End

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

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber(1)	2,083,343	416,657	416,657	$0.27	8/28/2016
	506,250	393,750	393,750	$0.47	8/29/2017
	700,000	2,100,000	2,100,000	$0.06	12/17/2018
Evan Myrianthopoulos	150,000	-	-	$0.35	11/14/2012
	50,000	-	-	$0.90	9/15/2013
	50,000	-	-	$0.58	6/11/2014
	150,000	-	-	$0.47	11/10/2014
	500,000	-	-	$0.49	12/13/2014
	375,000	25,000	25,000	$0.35	5/10/2016
	309,375	240,625	240,625	$0.47	8/29/2017
	300,000	900,000	900,000	$0.06	12/17/2018
James Clavijo	100,000	-	-	$0.45	10/22/2014
	150,000	-	-	$0.45	2/22/2015
	175,000	25,000	25,000	$0.33	5/10/2016
	187,500	112,500	112,500	$0.47	8/29/2017
	150,000	450,000	450,000	$0.06	12/17/2018

Compensation of Directors

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

Director Compensation

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

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

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

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the common stock as of February 11, 2009 of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Biotex Pharma Investments, LLC (1)	40,000,000	24.3%
Sigma-Tau Pharmaceuticals, Inc. (2)	43,213,537	26.3%
Cyrille F. Buhrman (3)	5,125,020	3.1%
Christopher J. Schaber (4)	3,877,499	2.3%
Evan Myrianthopoulos (5)	2,258,750	1.4%
James Clavijo (6)	881,941	*
James S. Kuo (7)	630,000	*
All directors and executive officers as a group (5 persons)	12,773,210	7.5%

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of February 11, 2009 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 164,524,739 shares of common stock outstanding as of February 11, 2009.

(1) Includes 20,000,000 shares of common stock and warrants to purchase 20,000,000 shares of common stock within 60 days of February 11, 2009. The address of Biotex Pharma Investments, LLC is c/o Biotex Pharma Investments, LLC 220 West 42nd Street 6th Floor New York, NY 10036.

(2) Includes 43,213,537 shares of common stock. The address of Sigma-Tau Pharmaceuticals, Inc. is c/o Sigma-Tau Pharmaceuticals, Inc., 800 South Frederick Avenue, Suite 300, Gaithersburg, Maryland 20877.

(3) Includes 4,900,020 shares of common stock and options to purchase 225,000 shares of common stock within 60 days of February 11, 2009. The address of Mr. Buhrman is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(4) Includes 392,766 shares of common stock owned by Dr. Schaber and options to purchase 3,484,733 shares of common stock within 60 days of February 11, 2009. The address of Dr. Schaber is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(5) Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife, options to purchase 1,943,750 shares of common stock and warrants to purchase 90,220 shares of common stock within 60 days of February 11, 2009. The address of Mr. Myrianthopoulos is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(6) Includes 88,191 shares of common stock owned by Mr. Clavijo and options to purchase 793,750 shares of common stock within 60 days of February 11, 2009. The address of Mr. Clavijo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

(7) Includes options to purchase 625,000 shares of common stock and warrants to purchase 5,000 shares of common stock within 60 days of February 11, 2009. The address of Dr. Kuo is c/o DOR BioPharma, 850 Bear Tavern Road, Suite 201, Ewing, New Jersey 08628.

Table of Contents

Equity Compensation Plan Information

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

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

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

SELLING STOCKHOLDERS

The following table presents information as of February 11, 2009 and sets forth the number of shares of common stock beneficially owned by each of the Selling Stockholders. We are not able to estimate the amount of shares that will be held by each Selling Stockholder after the completion of this offering because: (1) the Selling Stockholders may sell less than all of the shares registered under this prospectus; (2) the Selling Stockholders may exercise less than all of their warrants; and (3) to our knowledge, the Selling Stockholders currently have no agreements, arrangements or understandings with respect to the sale of any of their shares. The following table assumes that all of the shares being registered pursuant to this prospectus will be sold. The Selling Stockholders are not making any representation that any shares covered by this prospectus will be offered for sale. Except as otherwise indicated, based on information provided to us by each Selling Stockholder, the Selling Stockholders have sole voting and investment power with respect to their shares of common stock. Except as otherwise noted, none of the Selling Stockholders nor any of their affiliates have held a position or office, or had any other material relationship, with us.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Before the Offering (1)	Percent of Common Stock Owned Before the Offering	Shares Available for Sale Under This Prospectus (2)	Number of Shares of Common Stock To Be Owned After Completion of the Offering	Percent of Common Stock to be Owned After Completion of the Offering
Biotex Pharma Investments, LLC (3)	40,000,000	24.3%	20,000,000	-	*
Revach Fund LP (4)	701,754	*	701,754	-	*
Omacatl Capital, LTD (5)	1,150,696	*	438,596	712,100	*
Richard Molinsky	400,000	*	400,000	-	*
Bernard and Miriam Pismeny JT TEN	1,055,000	*	200,000	855,000	*
Robin B. Lipinski	1,271,720	*	87,720	1,184,000	*
Sigma-Tau Pharmaceuticals, Inc. (6)	43,213,537	26.3%	16,666,667	26,546,870	16.1%
Mark Tolpin	269,789	*	269,789	-	*
Martin S. Kratchman	21,875	*	21,875	-	*
John Andreadis	21,875	*	21,875	-	*
Little Gem Life Sciences Fund LLC (7)	1,023,999	*	300,000	723,999	*
Prospera Technology, LLC (8)	1,000,000	*	1,000,000	-	*
George B. McDonald, M.D.	1,600,000	*	1,000,000	600,000	*

Strategic Outsourcing Solutions, LLC (9)	50,000	*	50,000	-	*

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* Less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of February 11, 2009, are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 164,524,739 shares of common stock outstanding as of February 11, 2009.

(1) The shares of common stock issuable upon the exercise of warrants are as follows: Biotex Pharma Investments, LLC - 20,000,000 shares; Revach Fund LP - 350,877 shares; Omacatl Capital, LTD - 219,298 shares; Richard Molinsky - 200,000 shares; Bernard and Miriam Pismeny, JT TEN - 100,000 shares; Robin B. Lipinski - 43,860 shares; Mark Tolpin - 100,000; Little Gem Life Sciences Fund, LLC - 300,000; Prospera Technology, LLC - 1,000,000; George B. McDonald - 1,000,000; and Strategic Outsourcing Solutions, LLC - 50,000.

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

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

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

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

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

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

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

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

Table of Contents

47

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the Selling Stockholders. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to approximately $2,400,000 in proceeds from the exercise of the warrants to purchase our common stock. We intend to use the net proceeds from the exercise of the warrants as working capital to cover costs associated with the completion of the pivotal phase 3 clinical trial for orBec®, other research and development expenses, and general overhead costs including salaries until such time, if ever, as we are able to generate a positive cash flow from operations.

PLAN OF DISTRIBUTION

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

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

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

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

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

Upon our being notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the

participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon our being notified in writing by a Selling Stockholder that a donee or pledge intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

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

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

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

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

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 255,000,000 shares of capital stock, of which 250,000,000 shares are common stock, par value $0.001 per share, 4,600,000 shares are preferred stock, par value $0.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $0.05 per share, and 200,000 shares are Series C Convertible Preferred Stock, par value $0.05 per share. As of February 9, 2009, there were issued and outstanding 139,524,739 shares of common stock, options to purchase approximately 16,370,000 shares of common stock and warrants to purchase approximately 43,464,184 shares of common stock. The amount outstanding includes the 20,914,035 shares of common stock issued to the Selling Stockholders.

Common Stock

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

Preferred Stock

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

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

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is presently quoted on the Over-the-Counter Bulletin Board (“OTCBB”) under the symbol "DORB.” The amounts represent inter-dealer quotations without adjustment for retail markup, markdowns or commissions and do not represent the prices of actual transactions.

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

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of February 9, 2009, the last reported price of our common stock quoted on the OTCBB was $0.12 per share. The OTCBB price quoted reflects inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. We have approximately 1,072 registered holders of record.

Dividend Policy

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

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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

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

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

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

EXPERTS

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

LEGAL MATTERS

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

INDEX TO FINANCIAL STATEMENTS

DOR BIOPHARMA, Inc. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

	Page
Unaudited Consolidated Financial Statements-September 30, 2008:	
Consolidated Balance Sheet as of September 30, 2008	F-2
Consolidated Statements of Operations for the three months ended September 30, 2008 and 2007	F-3
Consolidated Statements of Operations for the nine months ended September 30, 2008 and 2007	F-4
Consolidated Statements of Cash Flows for the nine months ended September 30, 2008	F-5
Notes to Consolidated Financial Statements	F-6
Consolidated Financial Statements-December 31, 2007 and 2006:	
Report of Independent Registered Public Accounting Firm	F-9
Consolidated Balance Sheets as of December 31, 2007 and 2006	F-10
Consolidated Statements of Operations for the years ended December 31, 2007 and 2006	F-11
Consolidated Statements of Changes in Shareholders' Equity (Deficiency) for the years ended December 31, 2007 and 2006	F-12
Consolidated Statements of Cash Flows for the years ended December 31, 2007 and 2006	F-13
Notes to Financial Statements	F-14

Table of Contents

F-1

DOR BioPharma, Inc.
Consolidated Balance Sheet

	September 30, 2008	December 31, 2007
	(Unaudited)	
Assets		
Current assets:		
Cash	$ 686,216	$ 2,220,128
Accounts receivable	204,655	97,845
Inventory, net	83,182	-
Prepaid expenses	128,630	119,178
Total current assets	1,102,683	2,437,151
Office and laboratory equipment, net	21,896	25,941
Intangible assets, net	1,412,278	1,320,787
Total assets	$ 2,536,857	$ 3,783,879
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,361,360	$ 847,610
Accrued compensation	279,320	345,903
Total current liabilities	1,640,680	1,193,513
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 101,805,497 and 94,996,547, respectively issued and outstanding	101,805	94,996
Additional paid-in capital	102,793,670	101,391,090
Accumulated deficit	(101,999,298)	(98,895,720)
Total shareholders' equity	896,177	2,590,366
Total liabilities and shareholders' equity	$ 2,536,857	3,783,879

The accompanying notes are an integral part of these financial statements.

Table of Contents

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the three months ended September 30,
(Unaudited)

	2008	2007
Revenues	$ 605,736	$ 429,445
Cost of revenues	(538,182)	(301,672)
Gross profit	67,554	127,773
Operating expenses:		
Research and development	60,238	591,668
General and administrative	410,336	509,133
Stock based compensation research and development	39,584	77,362
Stock based compensation general and administrative	36,792	206,713
Total operating expenses	546,950	1,384,876
Loss from operations	(479,396)	(1,257,103)
Other income (expense):		
Interest income	5,391	10,121
Interest (expense)	(1,696)	-
Total other income (expense)	3,695	10,121
Net loss	$(475,701)	$(1,246,982)
BasicBBasic and diluted net loss per share	$ (0.00)	$ (0.01)
Basic Basic and diluted weighted average common shares outstanding	102,767,174	92,938,838

The accompanying notes are an integral part of these financial statements.

Table of Contents

DOR BioPharma, Inc.
Consolidated Statements of Operations
For the nine months ended September 30,
(Unaudited)

	2008	2007
Revenues	$ 1,771,620	$ 943,737
Cost of revenues	(1,459,206)	(669,882)
Gross profit	312,414	273,855
Operating expenses:		
Research and development	1,403,841	2,611,220
General and administrative	1,812,972	2,243,212
Stock based compensation research and development	118,750	164,890
Stock based compensation general and administrative	110,378	364,423
Total operating expenses	3,445,941	5,383,745
Loss from operations	(3,133,527)	(5,109,890)
Other income (expense):		
Interest income	32,248	144,062
Interest (expense)	(2,300)	(1,020)
Total other income (expense)	29,948	143,042
Net loss	$(3,103,579)	$(4,966,848)
Basic and diluted net loss per share	$ (0.03)	$ (0.06)
Basic and diluted weighted average common shares outstanding	100,478,733	89,389,416

The accompanying notes are an integral part of these financial statements.

Table of Contents

DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the nine months ended September 30,
(Unaudited)

	2008	2007
Operating activities		
Net loss	$ (3,103,579)	$ (4,966,848)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	107,804	84,475
Non-cash stock compensation	623,289	1,201,306
Change in operating assets and liabilities:		
Accounts receivable	(106,810)	(83,701)
Prepaid expenses	(9,452)	(53,467)
Accounts payable	514,452	(1,064,096)
Inventory	(83,182)	-
Accrued compensation	(67,784)	(271,102)
Total adjustments	978,317	(186,585)
Net cash used by operating activities	(2,125,262)	(5,153,433)
Investing activities:		
Acquisition of intangible assets	(191,350)	(294,404)
Purchase of office equipment	(3,400)	(10,182)
Net cash used by investing activities	(194,750)	(304,586)
Financing activities:		
Proceeds from sale of common stock	658,600	6,235,404
Proceeds from equity line	127,500	-
Proceeds from exercise of warrants	-	1,530,763
Proceeds from exercise of stock options	-	117,000
Net cash provided by financing activities	786,100	7,883,167
Net increase (decrease) in cash and cash equivalents	(1,533,912)	2,425,148
Cash and cash equivalents at beginning of period	2,220,128	119,636
Cash and cash equivalents at end of period	$ 686,216	$ 2,544,784
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 1,696	$ 413
Non-cash transactions:		
Non-cash stock payment to an institutional investor	$ 270,000	$ -

The accompanying notes are an integral part of these financial statements.

Table of Contents

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Basis of Presentation

These unaudited interim consolidated financial statements of the Company were prepared under the rules and regulations for reporting on Form 10-Q. Accordingly, the Company omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with the audited consolidated financial statements and their notes included in the Company's annual report on Form 10-KSB for the year ended December 31, 2007. In the Company's opinion, the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

The Company is a late stage biopharmaceutical company incorporated in 1987, focused on the development of biotherapeutic products and biodefense vaccines intended for areas of unmet medical need. DOR's biotherapeutic business segment intends to develop orBec®, oral BDP, and other biotherapeutic products namely LPMTM-Leuprolide, for Delivery of Water-Insoluble Drugs. DOR's biodefense business segment intends to convert its ricin toxin, botulinum toxin, and anthrax vaccine programs from early stage development to advanced development and manufacturing.

During the nine months ended September 30, 2008, the Company had two customers, the U.S. Federal Government and Orphan Australia Pty Ltd. ("Orphan Australia"), a specialty pharmaceutical company based in Melbourne, Australia, through a Named Patient Access Program ("NPAP") for orBec®. Revenues from the U.S. Federal Government were generated from three active grants. As of September 30, 2008 outstanding receivables were from the U.S. Federal Government, National Institute of Health and The U.S. Food and Drug Administration and Orphan Australia.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma, Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Segment Information

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

Accounts Receivable

Receivables consist of unbilled amounts due from grants from the National Institute of Health of the U.S. Federal Government and from Orphan Australia. The amounts were billed in the month subsequent to period end. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has

been established. If accounts become uncollectible, they are charged to operations.

Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes 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, all outside legal and filing costs incurred in the procurement and defense of patents are capitalized.

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

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from DOR’s academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its 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, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

Impairment of Long-Lived Assets

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

The Company did not record an impairment of intangible assets for either the three or nine months ended September 30, 2008 or 2007.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (“FIFO”) method and includes the cost of materials. The Company records an allowance as needed for excess inventory. For the three months ended September 30, 2008 an allowance of $100,000 was provided. This allowance will be evaluated on a quarterly basis and adjustments will be made as required. All inventory for this period is finished goods and consists of orBec® treatments.

Fair Value of Financial Instruments

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

Revenue Recognition

The Company's revenues are from government grants and NPAP sales of orBec® from Orphan Australia. The revenue from government grants are based upon subcontractor costs and internal costs covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when DOR incurs internal expenses that are related to the grant. The revenues from the NPAP sales of orBec® are recognized when the product is shipped.

Research and Development Costs

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

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment," effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company adopted SFAS No. 123R using the "modified prospective application" and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. The Company's net loss for the three months ended September 30, 2008 and 2007 pertaining to share-based compensation was $76,376 and $284,075 respectively; higher than if it had continued to account for share-based compensation under APB No. 25. For the nine months ended September 30, 2008 and 2007, the net loss was higher by $229,128 and $529,313 respectively. For the three months ended September 30, 2008, $39,584 of the $76,376 was for Research and Development personnel and $36,792 was for General and Administrative personnel. For the same period in 2007, $77,362 of the $284,075 was for Research and Development personnel and $206,713 was for General and Administrative personnel. For the nine months ended September 30, 2008, $118,750 of the $229,128 was for Research and Development personnel and the other $110,378 was for General and Administrative personnel. For the same period in 2007, $164,890 of the $529,313 was for Research and Development personnel and the other $364,423 was for General and Administrative personnel. 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. At September 30, 2008, the total compensation cost for stock options not yet recognized was approximately $380,000.

The fair value of each option grant at the three and nine months ended September 30, 2008 and September 30, 2007 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. The Company did not award any stock options for the three and nine months ended September 30, 2008 while 2,925,000 and 3,375,000 stock options were granted during the three and nine months ended September 30, 2007 respectively. The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.18 and $0.19 for the three and nine months ended September 30, 2007, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 99% and 100% in 2008 and 2007, respectively, and average risk-free interest rates of 3.9% and 4.5% in 2008 and 2007, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. Upon exercise, shares are issued from the 2005 stock option plan and increase the number of shares the Company has outstanding.

Shares repurchased

The Company from time to time evaluates whether to repurchase existing common stock shares in the marketplace. This repurchased stock would be reflected as Treasury Stock. The Company has not repurchased any shares during 2008. At this time we have no plans to repurchase the Company stock.

Income Taxes

The Company files a consolidated federal income tax return and utilizing asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through September 30, 2008 due to the net operating losses incurred by the Company since its inception.

Net Loss Per Share

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

Use of Estimates and Assumptions

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

3. Going Concern and Management's Plan

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. At September 30, 2008, the Company had a working capital deficit of $537,997 and a net loss of $3,103,579 for the nine months ended September 30, 2008. The Company also expects to sustain substantial losses over the next twelve months. Since its inception in 1987, the Company has incurred significant and recurring operating losses and negative cash flow from operations which raises substantial doubt about its ability to continue as a going concern. The Company's ability to continue its operations is dependent upon its ability to raise sufficient capital.

Management's plan is as follows:

- The Company is and will continue to seek capital in the private and/or public equity markets to continue its operations.
- The Company has implemented an austerity budget plan including suspension of its programs not supported by grant funding, reduction of office personnel, and reduction in overhead expenses.
    - The Company will also seek capital through licensing of orBec®.
- The Company is continuing to seek grant funds and to respond to requests for proposals from governmental sources.
- The Company has and will utilize Names Patient Sales wherever possible in countries outside the United States to generate revenues from orBec®.
- The Company is exploring outlicensing opportunities for LPM-Leuprolide and BioDefense programs in the United States and in Europe.
    - The Company has engaged investment bankers to assist in exploring merger and acquisition opportunities.

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

4. Accounts Receivable

In the third quarter of 2008, the Company recorded grant revenues from its three U.S. Government Grants in the amount of $565,118 and $40,618 from Orphan Australia for NPAP sales of orBec®. For the nine months ended September 30, 2008, recorded revenues were $1,771,620. Outstanding receivables at quarter end were $204,655. The receivables from the U.S. Government Grants and Orphan Australia have since been collected.

5. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2008				
Licenses	12.0	$ 462,234	$ 136,128	$ 326,106
Patents	9.2	1,824,839	738,667	1,086,172
Total	9.8	$ 2,287,073	$ 874,795	$ 1,412,278
December 31, 2007				
Licenses	12.7	$ 462,234	$ 115,681	$ 346,553
Patents	9.7	1,633,490	659,256	974,234
Total	10.4	$ 2,095,724	$ 774,937	$ 1,320,787

Amortization expense was $35,437 and $27,000 for the three months ended September 30, 2008 and 2007, respectively. Amortization expense was $99,859 and $75,300 for nine months ended September 30, 2008 and 2007, respectively.

Based on the balance of licenses and patents at September 30, 2008, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount

2008	$ 140,000
2009	140,000
2010	140,000
2011	142,000
2012	145,000

License fees and royalty payments are expensed annually.

6. Inventory

In the third quarter of 2008, the Company recorded inventory. Inventories are stated at the lower of cost or market. Cost is determined using the FIFO method and includes the cost of materials and overhead. Inventory consists of finished goods. For the nine month period ended September 30, 2008, the Company had $83,182 in inventory, as compared to $0 for the same period ended September 30, 2007. For the three month period ended September 30, 2008 the Company also recorded an allowance for excess inventory of $100,000.

7. Income Taxes

Deferred tax assets:

	September 30, 2008	December 31, 2007
Deferred tax assets:		
Net operating loss carry forwards	$ 27,400,000	$25,000,000
Orphan drug and research and development credit carry forwards	1,800,000	2,000,000
Other	3,000,000	3,000,000
Total	32,200,000	30,000,000
Valuation allowance	(32,200,000)	(30,000,000)
Net deferred tax assets	$ -	$ -

At December 31, 2007, the Company had net operating loss carry forwards of approximately $73,000,000 for Federal and state tax purposes, portions of which are currently expiring each year until 2026.

The following is the approximate amount of the Company’s tax credits and net operating loss carryforwards that expire over the next five years:

2008	$ 910,000
2009	1,330,000
2010	1,410,000
2011	870,000
2012	3,870,000

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2008 and 2007:

	2008	2007
Income tax loss at federal statutory rate	(34.00)%	(34.00)%

State taxes, net of federal benefit	(4.00)	(4.29)
Valuation allowance	38.00	38.29
Provision for income taxes (benefit)	- %	- %

Due to the move of the corporate offices to New Jersey, the Florida net operating loss carryforward is suspended.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to income tax assessment for years before 2004. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward to reduce taxable income generated in a given tax year.

8. Shareholders' Equity

During the three months ended September 30, 2008, the Company issued 26,516 shares of common stock as payment to vendors for consulting services. An expense of $3,500 was recorded which approximated the shares' fair market value on the date of issuance, respectively. During the three months ended September 30, 2008 the Company also issued 469,813 shares of common stock under its existing Fusion Capital Equity facility. The Company received $52,500 in proceeds and recorded $896 expense for the pro-rated commitment share expense which approximated the shares' fair market value on the date of issuance. During the nine months ended September 30, 2008, the Company issued 544,543 and 168,309 shares of common stock as payment to vendors for consulting services and as compensation and severance for employees, respectively. An expense of $95,812 and $25,864 was recorded which approximated the shares' fair market value on the date of issuance, respectively.

During the nine month period ended September 30, 2007, the Company issued 815,357 shares of common stock as payment to vendors for consulting services. An expense of $327,000 was recorded which approximated the shares' fair market value on the date of issuance. These shares of common stock were included in the Company's Form SB-2 Registration Statement filed with the SEC on March 9, 2007. Also during the nine months ended September 30, 2007, 6,208,287 warrants were exercised to purchase shares of common stock which provided proceeds of $1,530,763, 260,000 stock options were exercised to purchase shares of common stock which provided proceeds of $117,000, and 116,055 common stock shares were issued to employees as payment for payroll in lieu of cash in the amount of $36,250.

On February 14, 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital facility allows the Company to require Fusion Capital to purchase between $20,000 and $1.0 million every two business days, of the Company's common stock up to an aggregate of $8.0 million over approximately a 25-month period depending on certain conditions. As part of the agreement, the Company issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. The Company issued an additional 75,000 shares of common stock as a commitment fee in connection with this $500,000 purchase. If the Company's stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of the Company's common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company's common stock on any trading days that the market price of the Company's common stock is less than $0.10 per share. At this time the Company is unable to draw on Fusion because the Company's stock price is near or below $0.10 per share.

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

On February 9, 2007, the Company sold 11,680,850 shares of DOR's common stock to institutional investors and certain of the Company's officers and directors for a purchase price of $5,490,000.

On January 3, 2007, in consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and contributed an additional $2 million in cash. The $2 million contribution was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction's dilutive nature, all investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders in that placement who still held shares of the Company's common stock were issued additional shares as a cost basis adjustment from $0.277 to $0.246 per share of the Company's common stock. Neither these investors, nor

any others for that matter, hold any further anti-dilution rights. Because no agreement was reached by March 1, 2007, DOR was obligated to return the $2 million to Sigma-Tau by April 30, 2007. On June 1, 2007, the Company returned the $2 million to Sigma-Tau.

9. Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

10. Business Segments

The Company had two active segments for the three and nine months ended September 30, 2008 and 2007, respectively: BioDefense and BioTherapeutics. Summary data:

FOR THE THREE MONTHS ENDED

	September 30, 2008	2007
Net Revenues		
BioDefense	$ 565,118	$ 429,445
BioTherapeutics	40,618	-
Total	$ 605,736	$ 429,445
Loss from Operations		
BioDefense	$ 23,403	$ 25,676
BioTherapeutics	(305,920)	(581,363)
Corporate	(196,879)	(701,416)
Total	$ (479,396)	$ (1,257,103)
Identifiable Assets		
BioDefense	$ 962,575	$ 984,286
BioTherapeutics	584,358	511,690
Corporate	989,924	2,693,135
Total	$ 2,536,857	$ 4,189,111
Amortization and Depreciation Expense		
BioDefense	$ 17,462	$ 31,062
BioTherapeutics	14,679	3,462
Corporate	1,159	1,525
Total	$ 33,300	$ 36,049
Interest Income		
Corporate	$ 5,391	$ 10,121
Total	$ 5,391	$ 10,121
Stock Option Compensation		
BioDefense	$ 19,517	$ 34,027
BioTherapeutic	20,067	43,335
Corporate	36,792	206,713
Total	$ 76,376	$ 284,075

Table of Contents

F-7

FOR THE NINE MONTHS ENDED

	September 30, 2008	2007
Net Revenues		
BioDefense	$ 1,731,002	$ 943,737
BioTherapeutics	40,618	-
Total	$ 1,771,620	$ 943,737
Loss from Operations		
BioDefense	$ (151,938)	$ (51,010)
BioTherapeutics	(1,353,831)	(2,276,555)
Corporate	(1,627,758)	(2,782,325)
Total	$ (3,133,527)	$ (5,109,890)
Amortization and Depreciation Expense		
BioDefense	$ 61,160	$ 68,293
BioTherapeutics	42,671	11,593
Corporate	3,973	4,587
Total	$ 107,804	$ 84,473
Interest Income		
Corporate	$ 32,248	$ 144,062
Total	$ 32,248	$ 144,062
Stock Option Compensation		
BioDefense	$ 58,550	$ 63,387
BioTherapeutic	60,200	101,503
Corporate	110,378	364,423
Total	$ 229,128	$ 529,313

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of DOR BioPharma, Inc. and subsidiaries as of December 31, 2007 and 2006 and the related consolidated statements of operations, changes in shareholders' equity (deficiency) and cash flows for the years ended December 31, 2007 and 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years ended December 31, 2007, in conformity with United States generally accepted accounting principals.

/s/ Sweeney, Matz & Co., LLC

Pompano Beach, Florida
March 8, 2008

DOR BioPharma, Inc.
Consolidated Balance Sheets
December 31,

	2007	2006
Assets		
Current assets:		
Cash	$ 2,220,128	$ 119,636
Grants receivable	97,845	89,933
Prepaid expenses	119,178	94,470
Total current assets	2,437,151	304,039
Office and laboratory equipment, net	25,941	29,692
Intangible assets, net	1,320,787	1,073,239
Total assets	$ 3,783,879	$ 1,406,970
Liabilities and shareholders' equity (deficiency)		
Current liabilities:		
Accounts payable	$ 847,610	$ 2,112,479
Accrued compensation	345,903	402,947
Total current liabilities	1,193,513	2,515,426
Shareholders' equity (deficiency):		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 94,996,547 and 68,855,794, respectively issued and outstanding	94,996	68,855
Additional paid-in capital	101,391,090	91,553,766
	)	()
Accumulated deficit	(98,895,720	92,731,077
Total shareholders' equity (deficiency)	2,590,366	(1,108,456)
Total liabilities and shareholders' equity (deficiency)	$ 3,783,879	$ 1,406,970

The accompanying notes are an integral part of these financial statements.

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

	2007	2006
Revenues	$ 1,258,017	$ 2,313,020
Cost of revenues	(943,385)	(1,965,074)
Gross profit	314,632	347,946
Operating expenses:		
Research and development	3,099,944	3,638,493
General and administrative	2,864,370	2,553,700
Stock based compensation research and development	230,668	219,895
Stock based compensation general and administrative	446,733	337,287
In-process research and development	-	981,819
Impairment of intangible assets	-	816,300
Total operating expenses	6,641,715	8,547,494
Loss from operations	(6,327,083)	(8,199,548)
Other income (expense):		
Interest income	164,847	41,510
Interest (expense)	(1,020)	(5,308)
Other (expense)	(1,387)	-
Total other income (expense)	162,440	36,202
Net loss	$ (6,164,643)	$ (8,163,346)
BasicnBasic and diluted net loss per share	$ (0.07)	$ (0.13)
Basic Basic and diluted weighted average common shares outstanding	90,687,677	63,759,092

The accompanying notes are an integral part of these financial statements.

DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' (Deficiency)
For the years ended December 31, 2007 and 2006

	Common Stock		Additional Paid-In capital	AccumulatedDeficit
	Shares	Par Value		
Balance, January 1, 2006	50,612,504	$50,612	$86,045,192	($84,567,731)
Issuance of common stock	13,429,504	13,430	3,521,570	-
Issuance of common stock for exercise of options	504,100	504	112,816	-
Issuance of common stock to vendors	506,942	507	134,171	-
Issuance of warrants to vendors	-	-	121,965	-
Issuance of common stock for an equity commitment fee	512,500	512	(512)	-
Issuance of common stock to employees	222,061	222	82,632	-
Issuance of common stock to minority shareholders	3,068,183	3,068	978,750	-
Stock option expense	-	-	557,182	-
Net loss	-	-	-	(8,163,346)
Balance, December 31, 2006	68,855,794	$68,855	$91,553,766	($92,731,077)
Issuance of common stock	15,745,891	15,746	6,219,658	-

Issuance of common stock for exercise of options and warrants	8,195,487	8,195	2,218,088	-
Issuance of common stock to vendors	829,821	830	329,670	-
Issuance of stock to investors by contract as dilution protection	995,947	996	307,747	-
Issuance of common stock to employees	373,607	374	84,759	-
Stock option expense	-	-	677,401	-
Net loss	-	-	-	(6,164,643)
Balance, December 31, 2007	94,996,547	$94,996	$101,391,090	($98,895,720)

The accompanying notes are an integral part of these financial statements.

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

	2007	2006
Operating activities		
Net loss	$ (6,164,643)	$ (8,163,346)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	119,565	137,044
Non-cash stock compensation	1,401,777	896,680
Non-cash stock purchase of in-process research and development	-	981,819
Impairment expense for intangibles	-	816,300
Change in operating assets and liabilities:		
Grants receivable	(7,912)	474,397
Prepaid expenses	(24,708)	44,324
Accounts payable	(1,264,868)	476,605
Accrued compensation	(57,044)	254,347
Accrued royalties	-	(60,000)
Total adjustments	166,810	4,021,516
Net cash used by operating activities	(5,997,833)	(4,141,830)
Investing activities:		
Purchases of office and laboratory equipment	(7,170)	(2,552)
Acquisition of intangible assets	(356,192)	(206,004)
Net cash used by investing activities	(363,362)	(208,556)
Financing activities:		
Net proceeds from issuance of common stock	6,235,404	3,535,000
Proceeds from exercise of warrants	1,592,263	-
Proceeds from exercise of stock options	634,020	113,320
Net cash provided by financing activities	8,461,687	3,648,320
Net increase (decrease) in cash and cash equivalents	2,100,492	(702,066)
Cash and cash equivalents at beginning of period	119,636	821,702
Cash and cash equivalents at end of period	$ 2,220,128	$ 119,636
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 1,020	$ 3,170
Non-cash transactions:		
Non-cash payment to an institutional investor	$ -	$ 220,374

The accompanying notes are an integral part of these financial statements.

F-13

DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Nature of Business

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

During the year ending December 31, 2007, the Company had one customer, the U.S. Federal Government. All revenues were generated from two active U.S. Federal Government Grants. As of December 31, 2007 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated in consolidation.

Segment Information

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

Grants Receivable

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

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. The Company makes 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, all outside legal and filing costs incurred in the procurement and defense of patents are capitalized.

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

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. The Company believes that patent rights are one of its 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 the Company access to key product development rights from DOR's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its 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, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

Impairment of Long-Lived Assets

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

The Company recorded impairment of intangible assets of $0 and $816,300 for the years ended December 31, 2007 and 2006, respectively.

Fair Value of Financial Instruments

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

Revenue Recognition

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

Research and Development Costs

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

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment," effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company has adopted SFAS No. 123R using the "modified prospective application" and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. As a result of adopting SFAS No. 123R, the Company's net loss for the year ended December 31, 2007 was $677,401 and for December 31, 2006 was $557,182 higher than if it had continued to account for share-based compensation under APB No. 25. Of these amounts, $230,668 was for research and development and $446,733 was for general and administrative in 2007 and $219,895 was for research and development and $337,287 was for general and administrative in 2006. 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. At December 31, 2007, the total compensation cost for stock options not yet recognized was approximately $600,000.

The fair value of each option grant at the years ended December 31, 2007 and December 31, 2006 are estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. Stock options to purchase 3,375,000 share of common stock were granted for the year ended December 31, 2007 and stock options to purchase 4,360,000 shares of common stock were granted for the year ended December 31, 2006.

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.27 and $0.30 for 2007 and 2006, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 100% and 105% in 2007 and 2006, respectively, and average risk-free interest rates of 4.5% and 4.76% in 2007 and 2006, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest.

As stock options are exercised, common stock share certificates are issued via electronic transfer or physical share certificates by the Company's transfer agent. Shares are issued from the 1995 or 2005 stock option plan and increase the number of shares the Company has outstanding.

Shares repurchased

The Company from time to time evaluates whether to repurchase existing common stock shares in the marketplace. This repurchased stock would be reflected as Treasury Stock. At this time we have no plans to repurchase the Company stock.

Income Taxes

The Company files a consolidated federal income tax return and utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences

attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2007 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

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

Use of Estimates and Assumptions

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

New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157") which defines fair value, establishes a framework for measuring fair value and expands disclosure about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company has adopted SFAS No. 157 on January 1, 2008, as required, and is currently evaluating the impact of such adoption on its financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which is an interpretation of SFAS No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company has adopted the provisions of FIN 48 effective January 1, 2007.

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141(R)"). This statement provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to recognize all assets acquired and liabilities assumed in the transaction, establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed, and requires the acquirer to disclose the nature and financial effect of the business combination. The Company is currently assessing the impact to the Company's consolidated financial position, cash flows or results of operations upon adoption of SFAS 141(R).

In December 2007, the FASB issued SFAS No. 160, “Non-controlling Interests in Consolidated Financial Statements” (“SFAS 160”). This statement amends Accounting Research Bulletin No. 51, Consolidated Financial Statements, to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 141(R) and SFAS 160 are required to be adopted simultaneously and are effective for the first annual reporting period beginning on or after December 15, 2008, with earlier adoption prohibited. The Company is currently assessing the impact to the Company’s consolidated financial position, cash flows or results of operations upon adoption of SFAS 160.

3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At December 31, 2007, the Company had working capital of $1,243,638 and a net loss of $6,164,643. In the 12 months ended December 31, 2007, the Company raised a total of approximately $8,726,000, $6,500,000 of which was raised through equity financings and approximately $2,226,000 of which was raised from warrant and stock option exercises. Subsequent to December 31, 2007, the Company closed on an equity financing of $658,000 from Fusion Capital and other investors. Additionally, in February 2008 the Company initiated a 25 month, $8,000,000 equity line of credit with Fusion Capital. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be more difficult due to its receipt of a not approvable letter from the FDA on its NDA for orBec®.

If the Company is unable for whatever reason to utilize its equity facility with Fusion Capital and there were no other sources of financing, an austerity plan with reductions or discontinuation of operations of several of the Company's programs will be required. In an austerity plan, the Company would have to suspend clinical trials of orBec®/oral BDP for the treatment of GI GVHD and radiation enteritis, and reduce headcount and overhead. If this should occur, the Company believes it could continue to operate over the next four quarters at a reduced level and continue with its active programs, namely orBec® for the prevention of GVHD, its oral BDP radiation injury program, and its biodefense programs, all of which are supported by existing grants.

Management's plan to generate positive cash flows includes the following:

- The Company secured a new $8,000,000 equity line from Fusion Capital and the Company expects that the registration statement supporting this facility will become effective by April 2008.
- The Company will manage its expenditures very closely and proceed with Clinical programs with the use of the equity facility.
- The Company plans to continue seeking grant funds and responding to requests for proposals from governmental sources.
- The Company will utilize Named Patient Sales (Compassionate Use programs) wherever possible in countries outside the United States to generate revenues from orBec®. The Company already has letters of intent for Named Patient programs in place in South Korea, Australia, New Zealand and South Africa and expects to receive modest revenues from these programs in the second half of 2008.
- The Company is exploring outlicensing opportunities for orBec® and for its BioDefense programs both in the US and Europe.
- The Company has engaged investment bankers to assist in exploring mergers and acquisitions opportunities.

It is possible that the Company will seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, and develop new products and services and to support new strategic partnerships.

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

4. Office and Laboratory Equipment

Office and laboratory equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following at December 31:

	2007	2006
Office equipment	$ 125,328	$ 117,660
Laboratory equipment	23,212	23,212

Total	148,540	140,872
Accumulated depreciation	(122,599)	(111,180)
	$ 25,941	$ 29,692

Depreciation expense was $10,781 and $17,593 for the years ended December 31, 2007 and 2006, respectively.

5. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2007				
Licenses	12.7	$ 462,234	$ 115,681	$ 346,553
Patents	9.7	1,633,490	659,256	974,234
Total	10.4	$ 2,095,724	$ 774,937	$ 1,320,787
December 31, 2006				
Licenses	13.7	$ 462,234	$ 88,443	$ 373,791
Patents	8.8	1,277,157	577,709	699,448
Total	10.1	$ 1,739,391	$ 666,152	$ 1,073,239

Amortization expense was $108,784 in 2007 compared to $119,451 for 2006.

Based on the balance of licenses and patents at December 31, 2007, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2008	$ 125,000
2009	126,000
2010	127,000
2011	128,000
2012	129,000

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

In July 2003, the Company entered into an exclusive license agreement with University of Texas South Western ("UTSW") for administering the ricin vaccine via the intramuscular route for initial license fees of 250,000 shares valued at $200,000 of DOR common stock and $200,000 in cash. Subsequently, the Company negotiated the remaining intranasal and oral rights to the ricin vaccine for $50,000 in annual license fees in subsequent years. The license agreement's term is over the life of the patent.

On March 1, 2005, the Company signed a sponsored research agreement with UTSW extending through March 31, 2007 for $190,000 which will grant the Company certain rights to intellectual property.

In October 2003, the Company executed an exclusive license agreement with the University of Texas System ("UTMB") for the use of luminally-active steroids, including beclomethasone dipropionate (BDP) in the treatment of irritable bowel syndrome. Pursuant to this agreement, the Company paid UTMB a license fee of $10,000 and also agreed to pay an additional $10,000 license fee expense each year. The Company also agreed to pay past and future patent maintenance costs. The cost for 2007 and 2006 were $3,575 and $14,012, respectively. The Company acquired a sublicense agreement and may receive payments on this sublicense in the event of the sublicensee reaching certain milestones.

In July 2006, the Company signed a sponsored research agreement for $37,500 with Thomas Jefferson University ("TJU"). In 2005, the Company signed a sponsored research agreement for $150,000. In May 2003, the Company

signed a license agreement with TJU for the licensure of detoxified botulinum toxin for use as a vaccine. The Company paid TJU $30,000 in cash and issued 141,305 shares of common stock valued at $130,000. The Company also agreed to reimburse TJU for past and future patent maintenance. The patent maintenance expense for 2006 and 2005 was $74,260 and $35,665 respectively. The patent costs are capitalized. The Company is also responsible for a license maintenance fee of $10,000 in 2005 and $15,000 in 2006 and each year thereafter. These costs are expensed as incurred. The Company must also pay TJU $200,000, upon the first filing of any New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") and $400,000 upon first approval of an NDA relating to the first licensed product by FDA.

6. Shareholders' Equity

Preferred Stock

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

Common Stock

On February 9, 2007, the Company sold 11,680,850 shares of the Company's common stock to institutional investors and certain of the Company's officers and directors for a purchase price of $5,490,000.

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

On May 10, 2006, the Company completed a merger pursuant to which Enteron Pharmaceutical, Inc. ("Enteron"), the common stock of which the Company held 88.13% prior to the merger, was merged into a wholly-owned subsidiary of the Company. Pursuant to this transaction, the Company issued 3,068,183 shares of common stock to the Enteron minority shareholders in exchange for all of the outstanding common stock of Enteron that the Company did not already own. This transaction was accounted for as a purchase, and accordingly the Company recorded an in-process research and development expense of $981,819. The common stock was recorded at the shares' fair market value on the date of the merger.

On April 10, 2006, the Company sold 13,099,964 shares of common stock to institutional and other accredited investors for a purchase price, net of expenses, of $3,410,032. The investors also received warrants to purchase 13,099,964 shares of common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. The Company filed a registration statement with the SEC and it was declared effective on May 25, 2006.

On January 17, 2006, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. The Fusion Capital facility allowed them to purchase on each trading day $20,000 of the Company common stock up to an aggregate of $6,000,000 million over approximately a 15-month period. As part of that agreement, the Company issued Fusion Capital 512,500 shares of common stock as a commitment fee, the non-cash payment for this was $220,374 valued at the shares' fair market value. During 2006, Fusion Capital purchased 329,540 common shares for $ 124,968. The 2006 Fusion Capital agreement expired after the 15 month term of the contract expired.

Stock Compensation to Employees and Non-employees

During the years ended December 31, 2007 and 2006, the Company issued 829,821 and 506,942 shares of common stock, respectively, as payment to vendors for consulting services. An expense of $330,500 and $134,679, respectively, was recorded, which approximated the shares' fair market value on the date of issuance. Additionally, in

2007, the Company issued 373,607 shares of common stock as part of severance payments. In 2006, the Company issued 207,896 shares of common stock as part of severance payments to terminated employees and 165,711 shares of common stock to employees. An expense of $35,133 and $50,000, respectively, was recorded, which approximated the shares' fair market value on the date of issuance. In 2006, the Company issued 193,413 shares of common stock as part of severance payments to terminated employees and 28,648 shares of common stock to employees. An expense of $75,979 and $6,875, respectively, was recorded, which approximated the shares' fair market value on the date of issuance. These shares of common stock issued were covered by the Company's Form S-8 Registration Statement filed with the SEC on December 30, 2005 and amended in September 2007.

The dilutive nature of the Sigma-Tau transaction on January 3, 2007 required that all prior investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders who still held shares of the Company's common stock were issued 995,947 shares of the Company's common stock and the Company recorded an expense of $308,743. Neither these investors, nor any other investors, hold any further anti-dilution rights.

For the 12 months ended December 31, 2007, stock options were exercised to purchase 1,737,200 shares of common stock which provided $633,895 to the Company. For the corresponding period in 2006, 504,100 stock options were exercised to purchase shares of common stock which provided proceeds of $113,320 to the Company.

7. Stock Option Plans and Warrants to Purchase Common Stock

Stock Options

The 2005 Equity Incentive Plan is divided into four separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant. In addition under the plan the Board may elect to pay certain consultants, directors, and employees in common stock. The Plan was amended in September 2007 to increase the number of shares of common stock available under the plan to 20,000,000. The table below only accounts for transactions occurring as part of the amended 2005 Equity Incentive Plan.

December 31,	2007	2006
Shares available for grant at beginning of year	3,236,032	7,000,000
Increase in shares available	10,000,000	-
Options granted	(3,375,000)	(4,360,000)
Options forfeited or expired	1,140,000	1,325,000
Common stock payment for services	(388,071)	(728,968)
Shares available for grant at end of year	10,612,961	3,236,032

In 2007 and 2006, options were exercised to purchase 1,487,200 and 504,100 shares of common stock, respectively, that were covered under the 1995 plan.

The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2007 and 2006 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at January 1, 2006	10,014,339	$ 0.59
Granted	4,360,000	0.30
Forfeited	(2,230,900)	0.83
Exercised	(504,100)	0.22
Balance at December 31, 2006	11,639,339	0.59
Granted	3,375,000	0.46
Forfeited	(2,927,300)	0.73
Exercised	(1,737,200)	0.36
Balance at December 31, 2007	10,349,839	$ 0.44

The weighted-average exercise price, by price range, for outstanding options at December 31, 2007 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.20-$0.50	8.12	9,020,000	5,884,756
$0.51-$1.00	2.69	962,839	962,839
$1.01-$6.00	3.17	367,000	367,000
Total	7.53	10,349,839	7,214,595

Stock options are issued at the market price on the date of issuance. Stock options issued to directors fully vest upon issuance. Stock options issued to employees generally vest 25% upfront, then 25% each year for a period of three years. These options have a ten year life for as long as the individuals are employees or directors. In general when an employee or director terminates their relationship with the Company, the options will expire within three months.

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

Warrants to purchase common stock

Warrant activity for the years ended December 31, 2007 and 2006 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at January 1, 2006	22,167,118	$ 0.92
Granted	14,961,672	0.25
Balance at December 31, 2006	37,128,790	0.65
Granted	560,106	0.59
Expired	(2,178,909)	1.90
Exercised	(6,458,287)	0.25
Balance at December 31, 2007	29,051,700	$ 0.70

During 2006, warrants to purchase 500,000 shares of common stock were issued to vendors and an expense in the amount of $121,965 was recorded.

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

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2007 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.24-$0.50	1.23	8,503,386	8,503,386
$0.505-$1.00	1.67	18,328,622	18,328,622
$1.01-$2.00	0.29	2,012,622	2,012,622
$8.11	0.86	207,070	207,070
Total	1.44	29,051,700	29,051,700

8. Income Taxes

Deferred tax assets as of December 31:

	2007	2006
Deferred tax assets:		
Net operating loss carry forwards	$ 25,000,000	$25,000,000
Orphan drug and research and development credit carry forwards	2,000,000	3,000,000
Other	3,000,000	3,000,000
Total	30,000,000	31,000,000
Valuation allowance	(30,000,000)	(31,000,000)
Net deferred tax assets	$ -	$ -

At December 31, 2007, the Company had net operating loss carry forwards of approximately $73,000,000 for Federal and state tax purposes, which are currently expiring each year until 2026.

The net change in the valuation allowance for the year ended December 31, 2007 and December 31, 2006 was an increase of approximately $6,000,000 and $5,000,000 respectively, resulting primarily from net operating losses generated. Based on ownership changes that have and may occur, future utilization of the net operating loss carry forwards may be limited.

The following is the approximate amount of the Company’s tax credits and net operating losses that expire over the next five years:

2008	$ 910,000
2009	1,330,000
2010	1,410,000
2011	870,000
2012	3,870,000

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2007 and 2006 was as follows:

	2007	2006
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(4.29)	(3.63)
Permanent differences, principally purchased in-process research and development	-	3.30
Valuation allowance	38.29	34.33
Provision for income taxes (benefit)	- %	- %

Due to the move of the corporate offices to New Jersey, the Florida net operating loss is suspended.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to income tax assessment for years before 2004. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating losses to reduce taxable income generated in a given tax year.

9. Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

10. Concentrations

During the year ended December 31, 2007, the Company had one vendor that constituted approximately 12% of the outstanding payables.

At December 31, 2007 and 2006, the Company had deposits in financial institutions that exceeded the amount covered by the Federal Deposit Insurance Company. The excess amounts at December 31, 2007 and December 31, 2006 were $2,020,128 and $19,636, respectively. These funds are held at a major banking institution.

11. Subsequent Events

On February 14, 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. As part of the agreement, the Company issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. The Fusion Capital facility allows the Company to require Fusion Capital to purchase between $80,000 and $1,000,000 depending on certain conditions, of the Company’s common stock up to an aggregate of $8,500,000 over approximately a 25-month period. If the Company’s stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of the Company’s common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company’s common stock on any trading days that the market price of the Company’s common stock is less than $0.10 per share.

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

During November 2008, the Registrant issued 213,539 shares of common stock for services rendered to the Registrant. The value of these shares was approximately $15,000.

On December 1, 2008, the Registrant issued 16,666,667 shares of common stock in connection with the letter of intent entered into with Sigma-Tau Pharmaceuticals, Inc. for $1,500,000.

On January 20, 2009, the Registrant completed a private placement in which it issued 20,914,035 shares of common stock at $0.114 per share, and warrants to purchase 20,914,035 shares of common stock, resulting in net proceeds of $2,384,200. Also, as part of the compensation received for its assistance in the private placement, the placement agent received $114,000 cash and warrants to purchase an aggregate of 1,000,000 shares of the Registrant's common stock at an exercise price of $0.14 per share.

On February 11, 2009, the Registrant issued 25 million shares of common stock in connection with the collaboration and supply agreement entered into with Sigma-Tau Pharmaceuticals, Inc. for $4,500,000.

12. Business Segments

The Company had two active segments for the year ended December 31, 2007 and December 31, 2006: BioDefense and BioTherapeutics. Summary data:

	December 31, 2007	2006
Net Revenues		
BioDefense	$ 1,258,017	$ 2,173,128
BioTherapeutics	-	139,892
Total	$ 1,258,017	$ 2,313,020
Loss from Operations		
BioDefense	$ (109,699)	$ (1,973,732)
BioTherapeutics	(2,748,764)	(5,061,664)
Corporate	(3,468,620)	(1,164,152)
Total	$ (6,327,083)	$ (8,199,548)
Identifiable Assets		
BioDefense	$ 896,383	$ 849,295
BioTherapeutics	552,248	343,876
Corporate	2,335,248	213,799
Total	$ 3,783,879	$ 1,406,970
Amortization and Depreciation Expense		
BioDefense	$ 90,185	$ 103,855
BioTherapeutics	24,312	24,395
Corporate	5,068	8,794
Total	$ 119,565	$ 137,044
Interest Income		
Corporate	$ 164,847	$ 41,510
Total	$ 164,847	$ 41,510
Stock Option Compensation		
BioDefense	$ 69,591	$ 98,937
BioTherapeutic	161,077	120,958
Corporate	446,733	337,287
Total	$ 677,401	$ 557,182

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses of the Registrant in connection with the offering described in the registration statement.

SEC registration fee	$ 211
Legal fees and expenses	$15,000
Accounting fees and expenses	$ 2,000
Miscellaneous	$ 1,000
TOTAL	$18,211

ITEM 14. Indemnification of Directors and Officers.

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

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

Article VIII of the Registrant's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

The Registrant has a directors' and officers' liability insurance policy.

The above discussion is qualified in its entirety by reference to the Registrant's Certificate of Incorporation and Bylaws.

ITEM 15. Recent Sales of Unregistered Securities.

Under the terms of a Securities Purchase Agreement dated as of April 6, 2006 among the Registrant and the institutional and other accredited investors named therein, the Registrant issued 13,099,964 shares of its common stock to the investors, for aggregate gross proceeds of $3,630,000, and warrants, exercisable for three years, to purchase an aggregate of 13,099,964 shares of the Registrant's common stock at an exercise price of $0.45 per share. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

On January 3, 2007, the Registrant completed a private placement in which it issued 4,065,041 shares of common stock at $0.246 per share, resulting in net proceeds of $1 million. The shares of common stock were issued in transactions exempt from registration under the Securities Act, in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

Under the terms of a Securities Purchase Agreement dated as of February 9, 2007 among the Registrant and institutional investors and certain of its officers and directors named therein, the Registrant issued 11,680,850 shares of its common stock to the investors, for aggregate gross proceeds of $5,490,000. Also, as part of the compensation received for its assistance in the private placement, the placement agent received $259,950 cash and warrants to purchase an aggregate of 560,106 shares of the Registrant's common stock at an exercise price of $0.59 per share. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

On February 14, 2008, the Registrant entered into a common stock purchase agreement with Fusion Capital. Pursuant to the agreement, the Registrant issued to Fusion Capital 1,275,000 shares of common stock as a partial commitment fee, and 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

On February 14, 2008, the Registrant sold 881,112 shares of its common stock to institutional and other accredited investors for an aggregate purchase price of approximately $158,600. The investors also received four year warrants to purchase an aggregate of 440,556 shares of our common stock at an exercise price of $0.22 per share. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

During June 2008, the Registrant issued warrants to purchase up to 100,000 shares of common stock at an exercise price of $0.12 per share for services rendered to the Registrant. The warrants were offered in transactions exempt from registration under the Securities Act in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

During November 2008, the Registrant issued 213,539 shares of common stock for services rendered to the Registrant. The value of these shares was approximately $15,000. The shares of common stock were offered in transactions exempt from registration under the Securities Act in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

On December 1, 2008, the Registrant issued 16,666,667 shares of common stock in connection with the letter of intent entered into with Sigma-Tau Pharmaceuticals, Inc. for $1,500,000. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

During December 2008, the Registrant issued warrants to purchase up to 300,000 shares of common stock at an exercise price of $0.06 per share to Little Gem Life Sciences Fund, LLC for services rendered to the Registrant. The warrants were offered in transactions exempt from registration under the Securities Act in reliance

upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

On January 20, 2009, the Registrant completed a private placement in which it issued 20,914,035 shares of common stock at $0.114 per share, and warrants to purchase 20,914,035 shares of common stock, resulting in net proceeds of $2,384,200. Also, as part of the compensation received for its assistance in the private placement, the placement agent received $114,000 cash and warrants to purchase an aggregate of 1,000,000 shares of the Registrant's common stock at an exercise price of $0.14 per share. The shares of common stock were issued in transactions exempt from registration under the Securities Act, in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

During January 2009, the Registrant issued warrants to purchase up to 50,000 shares of common stock at an exercise price of $0.10 per share for services rendered to the Registrant. The warrants were offered in transactions exempt from registration under the Securities Act in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

On February 11, 2009, the Registrant issued warrants to purchase up to 1,000,000 shares of common stock at an exercise price of $0.11 per share to Dr. George B. McDonald for services rendered to the Registrant. The warrants were offered in transactions exempt from registration under the Securities Act in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

On February 11, 2009, the Registrant issued 25 million shares of common stock at an exercise price of $0.18 per share in connection with the collaboration and supply agreement entered into with Sigma-Tau Pharmaceuticals, Inc. for $4,500,000. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

ITEM 16. Exhibits.

2.1 Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).

3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

3.2 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 4.2 included in our Registration Statement on Form S-8 (File No. 333-130801) filed on December 30, 2005).

3.3 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Annex A to our Proxy Statement filed December 12, 2006).

3.4 By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).

3.5 Certificate of Designations of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2007).

4.1 Form of Investor Warrant issued to each investor dated as of April 12, 2000 (incorporated by reference to Exhibit 4.4 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.2 Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000 (incorporated by reference to Exhibit 4.5 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.3 Warrant issued to Aries Fund dated as of May 19, 1997 (incorporated by reference to Exhibit 4.6 included in our Registration Statement on Form S-3 (File No. 333-36950), as amended on December 29, 2000).

4.4 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997 (incorporated by reference to Exhibit 4.7 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.5 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(c) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.6 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(d) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.7 Warrant issued to Élan International Services, Ltd. Dated January 21, 1998 (incorporated by reference to Exhibit 4.4 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997).

4.8 Form of Warrant to be issued to CTD warrant holders (incorporated by reference to Exhibit 4.12 include in our Registration Statement on Form S-4 filed on October 2, 2001).

4.9 Form of Warrant issued to each investor in the December 2002 private placement (incorporated by reference to Exhibit 4.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2003).

4.10 Form of Warrant issued to each investor in the September 2003 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on July 18, 2003).

4.11 Form of Warrant issued to each investor in the March 2004 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on March 4, 2004).

4.12 Form of Warrant issued to each investor in the February 2005 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 3, 2005).

4.13 Form of Warrant issued to each investor in the April 2006 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on April 7, 2006).

4.14 Form of Warrant issued to finders in connection with the February 2007 private placement. (incorporated by reference to Exhibit 4.14 included in our registration statement on Form SB-2 filed on April 16, 2007).

4.15 Rights Agreement dated June 22, 2007, between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on June 22, 2007).

4.16 Form of Right Certificate (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on June 22, 2007).

4.17 Warrant dated February 14, 2008, issued to Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 4.17 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

4.18 Form of Warrant issued to each investor in the February 2008 private placement (incorporated by reference to Exhibit 10.2 in our current report on Form 8-K filed on January 21, 2009).

4.19 Form of Warrant issued to each investor in the January 2009 private placement (incorporated by reference to Exhibit 4.18 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

5.1 Opinion of Edwards Angell Palmer & Dodge LLP.*

10.1 Amended and Restated 1995 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

10.2 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 14, 2001).

10.3 Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001 (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.4 Termination of the Endorex Newco joint venture between the Company, Élan Corporation, Élan International Services, and Elan Pharmaceutical Investments dated December 12, 2002 (incorporated by reference to Exhibit 10.37 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.5 Option Agreement with General Alexander M. Haig Jr. (incorporated by reference to Exhibit 10.39 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.6 Separation agreement and General Release between the Company and Ralph Ellison dated July 9, 2004 (incorporated by reference to Exhibit 10.7 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.7 License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.8 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.8 License Agreement between the Company and Thomas Jefferson University (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.9 License Agreement between the Company and the University of Texas Medical Branch (incorporated by reference to Exhibit 10.10 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.10 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (incorporated by reference to Exhibit 10.43 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.11 Form of Subscription Agreement between the Company and each investor dated July 18, 2003 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on July 18, 2003).

10.12

Form of Securities Purchase Agreement between the Company and each investor dated March 4, 2004 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on March 4, 2004).

10.13 Employment agreement between the Company and Mike Sember dated December 7, 2004 (incorporated by reference to Exhibit 10.16 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.14 Employment agreement between the Company and Evan Myrianthopoulos dated December 7, 2004 (incorporated by reference to Exhibit 10.17 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.15 Employment agreement between the Company and James Clavijo dated February 18, 2005 (incorporated by reference to Exhibit 10.18 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.16 Form of Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 3, 2005).

10.17 Amendment No. 1 dated February 17, 2005 to the Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.20 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.18 Form Registration Rights agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on February 3, 2005).

10.19 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005).

10.20 Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).

10.21 Form of Securities Purchase Agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 20, 2006)

10.22 Form of Registration Rights agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on January 20, 2006).

10.23 Securities Purchase Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on April 7, 2006).

10.24 Registration Rights Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on April 7, 2006).

10.25 Employment Agreement, dated as of August 29, 2006, between Christopher J. Schaber, Ph.D., and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on August 30, 2006).

10.26 Letter of Intent dated January 3, 2007 by and between DOR BioPharma, Inc. and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 4, 2007).

10.27 January 17, 2007 letter from Cell Therapeutics, Inc. to DOR BioPharma, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 19, 2007).

10.28 Securities Purchase Agreement dated February 7, 2007 by and among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 12, 2007).

10.29 Registration Rights Agreement dated February 7, 2007 by among the Company and the investors named therein (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 12, 2007).

10.30 Letter from Sigma-Tau Pharmaceuticals, Inc. dated February 21, 2007 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 23, 2007).

10.31 Letter dated May 3, 2007 between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on May 4, 2007).

10.32 Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 28, 2007).

10.33 Employment Agreement dated December 27, 2007, between Evan Myrianthopoulos and the Company (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on December 28, 2007).

10.34 Employment Agreement dated December 27, 2007, between James Clavijo, CPA and the Company (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 28, 2007).

10.35 Common Stock Purchase Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.35 included on Form S-1 filed on February 14, 2008).

10.36 Registration Rights Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.35 included in our Registration Statement on Form S-1 (File No. 333-149239) on Form S-1 filed on February 14, 2008).

10.37 Letter dated December 1, 2008, between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our

current report on Form 8-K filed on December 1, 2008).

10.38 Form of Securities Purchase Agreement between the Company and each investor dated February 14, 2008 (incorporated by reference to Exhibit 10.37 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).

10.39 Common Stock Purchase Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 21, 2009).

10.40 Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21, 2009).

10.41 Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21, 2009).

10.42 Exclusive License Agreement dated November 24, 1998, between Enteron Pharmaceuticals, Inc. and George B. McDonald, M.D.*

10.43 Collaboration and Supply Agreement dated February 11, 2009, betweeen the Company and Sigma-Tau Pharmaceuticals, Inc.*†

10.44 Common Stock Purchase Agreement dated February 11, 2009, between the Company and Sigma Tau Pharmaceuticals, Inc.*

23.1 Consent of Sweeney, Matz & Co., LLC, independent registered public accounting firm.*

23.2 Consent of Edwards Angell Palmer & Dodge LLC (contained in the opinion filed as Exhibit 5.1 hereto).*

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* Filed herewith.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

ITEM 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

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

In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ewing, State of New Jersey, on the 13th day of February 2009.

DOR BIOPHARMA, INC.

By: /s/ Christopher J. Schaber, Ph.D.
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher J. Schaber and Evan Myrianthopoulos, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, to sign any or all amendments to this Registration Statement on Form S-1 (including post-effective amendments), and to file the same, with all exhibits thereto, and other documents in connection therewith with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully and to all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christopher J. Schaber, Ph.D. Christopher J. Schaber, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	February 13, 2009
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Director and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 13, 2009
/s/ James S. Kuo James S. Kuo	Chairman of the Board	February 13, 2009