DOR BIOPHARMA INC
Form S-1
January 20, 2006

As filed with the Securities and Exchange Commission on January 20, 2006.
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.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**41-150502**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Identification No.)

DOR BioPharma, Inc.
Lincoln Building, 1691 Michigan Ave
Miami, Florida 33139
(305) 534-3383
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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

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

(954) 727-2600

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered	Proposed maximum offering price per unit (1)	Proposed maximum aggregate offering price (1)	Amount of registration fee(1)
Common Stock, $.001 par value per share(2)(3)	9,962,500	$0.27	$2,689,875	$287.82

(1) Estimated solely for purposes of calculating the registration fee according to Rule 457(c) under the Securities Act of 1933, as amended, on the basis of the average of the high and low prices of the Registrant's common stock reported on the American Stock Exchange on January 12, 2006.
(2) In the event that the shares registered in this prospectus are insufficient to meet the delivery requirements at the actual time of the put date settlement, the Registrant will file a new registration statement to register the additional shares.
(3) All of the shares of common stock registered in this registration statement will be sold by the selling security holder.

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

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

SUBJECT TO COMPLETION, DATED JANUARY 20, 2006

PROSPECTUS

DOR BioPharma, Inc.

9,962,500 Shares of Common Stock

This prospectus relates to the sale of up to 9,962,500 shares of our common stock by Fusion Capital Fund II, LLC. Fusion Capital is sometimes referred to in this prospectus as the selling stockholder. The prices at which Fusion Capital may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Fusion Capital.

Our common stock is quoted on the American Stock Exchange under the symbol "DOR." On January 13, 2006, the last reported sale price for our common stock as reported on the American Stock Exchange was $0.29 per share. We have applied to have the shares of common stock offered pursuant to this prospectus approved for trading on the American Stock Exchange.

Investing in the common stock involves certain risks. See "Risk Factors" beginning on page 5 for a discussion of these risks.

The selling stockholder is an "underwriter" within the meaning of the Securities Act of 1933, as amended.

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.

The date of this prospectus is January 20, 2006

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

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

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

FORWARD-LOOKING STATEMENTS

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

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

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

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

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or

circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

PROSPECTUS SUMMARY

The Company

We are a biopharmaceutical company focused on the development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. Our business strategy is to (a) prepare the submission of a New Drug Application, ("NDA") for orBec® with the U.S. Food and Drug Administration, ("FDA") for the treatment of intestinal Graft-versus-Host Disease, "iGVHD"; (b) consider prophylactic use studies of orBec® for the prevention of iGVHD; (c) evaluate and possibly initiate additional clinical trials to explore the effectiveness of oral BDP (orBec®) in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract; (d) identify a marketing and sales partner for orBec® for territories outside of the U.S., and potentially inside the U.S.; (e) secure government funding for each of our biodefense programs through grants, contracts, and procurements; (f) convert the biodefense vaccine programs from early stage development to advanced development and manufacturing; (g) transition the biodefense vaccine development programs from academic institutions into commercial manufacturing facilities with the goal of soliciting government contracts; (h) identify the development candidates for botulinum therapeutic screening program; and (i) acquire or in-license new clinical-stage compounds for development.

orBec®

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

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

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

RiVax™

The scientific development of RiVax™, our ricin toxin vaccine, has progressed significantly this year. We initiated a Phase I safety and immunogenicity trial in February of this year and in June we announced positive interim safety and immunogenicity data. In January of this year we entered into a manufacturing and supply agreement for RiVax™ with Cambrex Corporation. We recently announced that Cambrex has successfully achieved the first milestone of fermentation and downstream process development under their development and manufacturing agreement. RiVax™ is being developed for intramuscular delivery. We are also working on a formulation technology that could permit the vaccine to be delivered nasally, with the objective of providing immunity in the respiratory tract.

Botulinum Programs

BT-VACC™

Our mucosal botulinum toxin vaccine program has made important strides this year. We are developing a mucosal vaccine against botulinum neurotoxins serotypes A, B and E, which account for almost all human cases of disease. We have identified lead antigens against Serotypes A and B consisting of the Hc50 fragment of the botulinum toxin. Our preclinical data to date, demonstrates that Hc50, A and B are completely effective at low, mid and high doses as an intranasal vaccine and completely effective at the higher dose level orally in mice and rats. Ongoing studies are focused on serotype E; multivalent immunization experiments using serotype A, B and E antigens given simultaneously to animals and formulation work to create a microencapsulated, enterically formulated oral dosage form, which we anticipate will be a more active and stable oral formulation improving immunogenicity and potency. To date much of the preclinical work is being conducted at Thomas Jefferson University under a sponsored research agreement funded by us. We have applied for and intend to continue to apply for research grants and contracts from the U.S. government to continue development of this vaccine. We have also recently entered into a joint development agreement with Dowpharma, a business unit of the Dow Chemical Company. Dowpharma is providing process development leading to current Good Manufacturing Practices (cGMP) production services for BT-VACC™ using its Pfēnex Expression Technology™, a *Pseudomonas*-based technology that accelerates speed to market for vaccines and biotherapeutics by surpassing the quality and yield capabilities of existing microbial systems. In a very short duration, we have demonstrated successful high expression of soluble material from all three Hc50 fragments.

Botulinum Therapeutics

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

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

Material Letter of Intent - Acquisition of Gastrotech Pharma

On October 28, 2005, we entered into a binding letter of intent to acquire Gastrotech Pharma A/S (“Gastrotech”), a private Danish biotechnology company developing therapeutics based on gastrointestinal peptide hormones to treat gastrointestinal and cancer diseases and conditions. Gastrotech develops therapeutics based on peptide hormones to treat cancer and gastrointestinal (GI) diseases and conditions. Gastrotech was founded on technology developed at the Sahlgrenska University Hospital in Sweden.

Following the closing of this acquisition, our pipeline will be bolstered by the addition of two Phase 2 programs: GTP-010, an analogue of glucagon-like peptide-1 (“GLP-1”), and GTP-200, Gastrotech’s wild type ghrelin compound, a naturally occurring peptide hormone produced in the stomach to stimulate appetite. GTP-010 is being studied in collaboration with Eli Lilly in a Phase 2, double-blinded, placebo-controlled trial for the treatment of pain associated with irritable bowel syndrome (“IBS”). The product also has application in the treatment of functional dyspepsia. GLP-1 has been shown to reduce the gastrointestinal contractions associated with IBS and other GI disorders.

Preclinical and clinical studies have demonstrated GTP-200’s positive effect on regulation of appetite, food intake, and metabolism. Cancer cachexia is estimated to be a $4 billion market and an unmet medical need affecting 50% of all

cancer patients and fatal in 40% of patients. GTP-200 completed patient treatment in a Phase 1/2 clinical trial for the treatment of cancer cachexia in September 2005. Results from this study will be available in early 2006. GTP-200 is also being evaluated for the treatment of gastrectomized patients as well as for several other indications.

In connection with the closing of the acquisition, we will issue the stockholders of Gastrotech $9 million in our common stock priced at the 10-day volume weighted average price immediately prior to the closing. In no event will we issue less than 20 million or more than 30 million shares of our common stock to Gastrotech's shareholders. This corresponds to a price collar on the transaction of between $0.30 and $0.45 per share of our common stock. We will also issue to the new December 2005 investors in Gastrotech $1.9 million in our common stock priced at the 10-day volume weighted average price immediately prior to the closing. The shares issued to the Gastrotech shareholders at closing would represent up to 41.9% of our outstanding shares following such transaction, assuming we issue the maximum of 30 million shares for the $9 million of our common stock and 6,551,724 shares of our common stock for the additional $1.9 million (assuming for purposes of this calculation a stock price of $0.29, the closing sale price of our common stock on January 13, 2006). In addition, we will pay Gastrotech shareholders another $30 million upon the occurrence of the following milestones: $4 million in stock priced at the time of initiation of a pivotal Phase 3 study of any of Gastrotech's compounds, $6 million in stock priced at the time of filing of an NDA for any of Gastrotech's compounds, $10 million payable in cash or stock when either of Gastrotech's compounds achieves $50 million in sales in any calendar year, and $10 million payable in cash or stock when either of Gastrotech's compounds achieves $200 million in sales in any calendar year. The parties intend that the acquisition would include the transfer of Gastrotech's ongoing clinical programs to us as well as all intellectual property and facilities.

The closing of the acquisition is subject to the negotiation of definitive agreements between the parties containing representations, warranties, covenants, and conditions which are typically included in transactions of this nature and to completion of due diligence on Gastrotech's intellectual property by our outside patent counsel. We have agreed to register the shares issued to the Gastrotech stockholders for resale under the Securities Act of 1933. The largest Gastrotech stockholder has agreed to limit its sales of our common stock to 20% of its holdings per quarter. We have agreed to expand our Board of Directors to nine members, with three positions being appointed by the Gastrotech stockholders. There is a breakup fee of $1.0 million if either party breaches the terms of the binding letter of intent.

THE OFFERING

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions, including that the registration statement of which this prospectus is a part of is declared effective by the SEC, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over approximately a 15 month period, subject to earlier termination at our discretion. In our discretion, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12.

Fusion Capital is offering for sale up to 9,962,500 shares of our common stock. In the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,117,439, i.e., greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

As of January 13, 2006, there were 50,612,504 shares outstanding, excluding the 9,962,500 shares offered by Fusion Capital pursuant to this prospectus which have not yet been issued by us. If all of the shares offered by this prospectus were issued and outstanding as of the date hereof, the number of shares offered by this prospectus would represent

approximately 16.4% of the total common stock outstanding as of January 13, 2006.

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

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and related notes.

Risks Related To Our Industry

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

We are a company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2005, we had approximately $1.8 million in cash available. We expect that we will need additional sources of funding to meet our cash requirements for the next twelve months. In addition, through a National Institute of Health grant, a portion of our personnel and overhead expenditures will be supported. All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through September 30, 2005, we had expended approximately $12.2 million developing our current product candidates for preclinical research and development and clinical trials, and we currently expect to spend at least $8.0 million over the next two years in connection with the development and commercialization of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our leading product candidate, or another one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

We only have the right to receive $20,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $0.12. Since we initially registered 9,000,000 shares for sale by Fusion Capital pursuant to this prospectus (excluding the 900,000 commitment fee shares and 62,500 expense reimbursement shares that we have registered), the selling price of our common stock to Fusion Capital will have to average at least $0.67 per share for us to receive the maximum proceeds of $6.0 million without registering additional shares of common stock. Assuming a purchase price of $0.29 per share (the closing sale price of the common stock on January 13, 2006), proceeds to us would only be $2,610,000 unless we choose to

register more than 9,962,500 shares, which we have the right to do. Subject to approval by our board of directors, we have the right under the common stock purchase agreement to issue more than 9,962,500 shares to Fusion Capital. In the event we elect to issue more than 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the U.S. Securities & Exchange Commission.

In addition, in the event that we decide to issue more than 10,117,439 (19.99% of our outstanding shares of common stock as of the date of our agreement), we would first be required to seek stockholder approval in order to be in compliance with the American Stock Exchange rules. We currently do not intend to seek stockholder approval to effect sales to Fusion Capital in excess of 10,117,439 shares.

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

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

·we will not be able to maintain our current research and development schedules;

·we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;

·we will encounter problems in clinical trials; or

·the technology or product will be found to be ineffective or unsafe.

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

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

·we are not able to enter into arrangements or collaborations to manufacture and/or market the product;

·the product is not eligible for third-party reimbursement from government or private insurers;

·others hold proprietary rights that preclude us from commercializing the product;

·others have brought to market similar or superior products; or

·the product has undesirable or unintended side effects that prevent or limit its commercial use.

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

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

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

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

There may be unforeseen challenges in developing biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine is 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 almost entirely upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If the Gastrotech acquisition is completed, the integration of Gastrotech into our operations involves numerous risks which could cause our business and growth prospects could suffer.

We have signed a binding letter of intent to acquire Gastrotech. The closing of the acquisition is subject to execution of definitive agreements between the parties, containing such representations, warranties, covenants, conditions, indemnities and limitations on the Gastrotech stockholders' liability as are customary in a transaction of this kind. There can be no assurance that we will be successful in negotiating definitive agreements between the parties, or that if we enter into definitive agreements, that we will consummate the acquisition.

If we complete the Gastrotech acquisition, the integration of an acquired business into our operations involves numerous risks, including difficulties in integrating an acquired company's hardware and software products and services with our own; the diversion of our resources and management's attention from other business concerns; the

potential loss of key employees; the need for greater amounts of working capital to support the newly combined company and the day-to-day management of a substantially larger and more geographically diverse combined company. In addition, we may not realize the synergies, operating efficiencies, market position or revenue growth we anticipate from this acquisition and our failure to effectively manage the above risks and other problems associated with the acquisition could have a material adverse effect on our business, growth prospects and financial performance.

This acquisition also poses the risk that we may be exposed to successor liability relating to actions by Gastrotech and its management before the acquisition. The due diligence we conduct in connection with this acquisition, and any contractual indemnities we may receive from the shareholders of Gastrotech, may not be sufficient to protect us from, or compensate us for, actual liabilities. A material liability associated with this acquisition could also adversely affect our financial position and reduce the anticipated benefits of the acquisition.

Risks Related to the Offering

Our stock price is highly volatile.

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

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

Our per share stock price has fluctuated between January 1, 2001 through January 13, 2006 between a high of $2.10 per share to a low of $0.11 per share. As of January 13, 2006, the closing sale price of our common stock was $0.29. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Our stock may not remain listed on the American Stock Exchange

Because we continue to incur losses from operations in fiscal 2005, the stockholders' equity standard applicable to us of the American Stock Exchange's (AMEX) continued listing requirements is $6 million. As of September 30, 2005, we had stockholders' equity of $3,519,342.

In June 30, 2003, our net equity of $2.3 million did not satisfy the $4 million minimum stockholders' equity requirement that was applicable to calendar quarters ending during 2003, and we received notification from the AMEX that we were no longer in compliance with their minimum listing requirements. This requirement was increased to $6 million minimum stockholders' equity for fiscal years ending 2003 and beyond. On August 4, 2003 we submitted a compliance plan, and the AMEX accepted our plan and allowed us 18 months to regain compliance in accordance with the terms of our plan. Our deadline to meet the plan was December 26, 2004, to avoid delisting from the AMEX. Although we did not meet the plan submitted, AMEX provided us with the opportunity to submit a new plan of compliance with the listing standard, which we submitted on December 30, 2004. On January 24, 2005 AMEX accepted the compliance plan and provided us until July 12, 2005 to comply with the continued listing standard of section 1003 (a) (iii) of the AMEX company guide. This compliance date was then extended by AMEX until October 15, 2005. On such date, we did not have $6 million in stockholders' equity. Therefore on October 26, 2005, the Company received notice from the AMEX staff indicating that the Company no longer complies with AMEX's continued listing standards because the Company had shareholders' equity of less than $6.0 million and losses from continuing operations and/or net losses in its five most recent fiscal years, as set forth in Section 1003(a)(iii) of the Company Guide, and that the AMEX intends to proceed with removal of the Company's common stock from listing and registration on AMEX. The Company appealed this determination and requested a hearing before a committee of the AMEX which was held on December 2, 2005. In addition, on November 22, 2005, the Company received notice from the AMEX staff indicating that the Company also no longer complies with AMEX's continued listing standards because the Company had shareholders' equity of less than $4.0 million and losses from continuing operations and/or net losses in three of its four most recent fiscal years, as set forth in Section 1003(a)(iii) of the Company Guide. AMEX also considered this deficiency at the hearing on December 2, 2005. On December 8, 2005, we received notice from AMEX that we had been granted an extension until March 31, 2006 to regain compliance with AMEX's rules. If we have not done so by that date, AMEX will delist us with no further opportunity to appeal. We cannot assure you that we will regain compliance by March 31, 2006 nor can we assure you that we will continue to satisfy other requirements necessary to remain listed on the AMEX or that the AMEX will not take additional actions to delist our common stock.

If our stock were to be delisted from the AMEX, we may not be able to list our common stock on another national exchange or market. If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Upon any such delisting, our common stock would become 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, if our common stock were to become subject to the penny stock rules, it is likely that the price of our common stock would decline and that our stockholders would find it more difficult to sell their shares.

Stockholders 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 22.2 million shares of our common stock at a

current weighted average exercise price of approximately $0.93;

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

- options to purchase approximately 10.3 million shares of our common stock at a current weighted average exercise price of approximately $0.59.

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

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. See "—Holders of our common stock are subject to the risk of additional and substantial dilution to their interests as a result of the issuances of common stock to Fusion Capital." We are also involved in negotiations that could result in the issuance of a significant number of shares of our equity securities. This transaction as well as the issuances in the Gastrotech acquisition could result in substantial dilution to our existing stockholders.

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

We cannot begin sales of our common stock to Fusion Capital until the effectiveness of the registration statement of which this prospectus is a part and the common stock purchase agreement may be terminated in the event of a default under the agreement. In addition, Fusion Capital does not have the right or the obligation to purchase any shares of our common stock if the purchase price is less than $0.12 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. See "Fusion Transaction."

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

Shareholders are subject to the risk of substantial dilution to their interests as a result of our issuance of shares under the common stock purchase agreement. The sale by the selling stockholder of our common stock as contemplated by this prospectus will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by the selling stockholder as contemplated by this prospectus could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock. In addition, in the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. If such registration were declared effective by the SEC, Fusion Capital could also sell any shares registered on such a subsequent registration statement and this in turn would result in additional dilution to our other stockholders. If we elect to issue more than the 9,962,500 shares offered hereby and the average price at which we sell $6.0 million of our stock is $0.29 (the closing sale price of our common stock on January 13, 2006) we would issue 20.7 million shares. We do not have the right to sell shares to Fusion Capital at a price below $0.12 per share and accordingly we could not issue more than 50,000,000 shares under the agreement.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares in this offering are freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the

shares offered by this prospectus will be sold over a period of in excess of 15 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this offering, 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.

The Gastrotech, Fusion and other contemplated transactions could cause our stock to be held by a small group of stockholders and result in a change in control.

Following consummation of the Gastrotech transactions, the former Gastrotech stockholders potentially could beneficially own up to 41.9% of our outstanding shares following such transaction, assuming we issue the maximum of 30 million shares for the $9 million of our common stock and 6,551,724 shares of our common stock for the additional $1.9 million (assuming for purposes of this calculation a stock price of $0.29, the closing sale price of our common stock on January 13, 2006). In addition, we are presently involved in negotiations that could result in the issuance of an additional significant number of shares of senior equity securities to a small number of investors that, if successful, could result in a change in control in a series of one or more transactions. Either Gastrotech's shareholders or such potential new investors would be able to effectively or actually control all matters requiring approval by stockholders, including the election of directors, the approval of amendments to our charter and approval of significant corporate transactions. The interests of these stockholders may differ from the interests of other stockholders since they may be issued with rights and preferences that are senior to those of our current stockholders, and their concentration of ownership could have the effect of causing our current stockholders to lose the control premium currently associated with their shares by denying stockholders the ability to vote upon subsequent change in control transactions of the company. Depending upon the structure of such one or more series of new issuance of stock, stockholders may not be afforded an adequate opportunity to vote on the terms of such series of transactions. Such potential concentration of ownership or change in control could also have the effect of delaying or preventing a change in control of our business or otherwise discouraging a potential acquiror from attempting to take control of us, even if the transactions would be beneficial to our other stockholders.

If the market price of our common stock declines, we may be unable to utilize the Fusion Capital agreement without requesting our shareholders to approve the issuance of more than 19.99% of our common stock or registering additional shares, both of which would impose additional costs and time delays.

If the market price of our common stock declines, the number of shares of common stock issuable in connection with the Fusion Capital agreement will increase. Accordingly, we may be required to ask our shareholders to approve issuances over 19.99% of our common stock as required under AMEX rules or we may run out of shares registered under this registration statement to issue to the investor in connection with our use of the Fusion Capital agreement. In such an event, we would be required to ask our shareholders to approve such issuance and/or would be required to file additional registration statements to cover the resale of additional shares, both of which would impose additional costs and time delays.

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

Our common stock has from time to time been "thinly-traded", meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a

large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Fusion Capital's purchase and sale into the market of $20,000 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. Using the closing price on January 13, 2006, of $0.29 as an example, Fusion Capital would be issued approximately 68,966 shares each trading day if we elected to have them purchase the $20,000 daily purchase amount, whereas our average trading volume for the three months ending on January 13, 2006, is approximately 145,185 per day. 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 each trading day which would increase the dilution of your investment. Although we have the right to reduce or suspend Fusion Capital purchases at any time, our financial condition at the time may require us to waive our right to suspend purchases even if there is a decline in the market price.

Contractual 9.9% beneficial ownership limitations prohibit Fusion Capital, together with its affiliates, from beneficially owning more than 9.9% of our outstanding common stock. This 9.9% limitation does not prevent Fusion Capital from purchasing shares of our common stock and then reselling those shares in stages over time so that Fusion Capital and its affiliates do not, at any given time, beneficially own shares in excess of the 9.9% limitation. Consequently, these limitations will not necessarily prevent substantial dilution of the voting power and value of your investment.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a Registration Statement on Form S-1 with all amendments and exhibits under the Securities Act of 1933, concerning the common stock offered in this prospectus. This prospectus does not contain all of the information contained in the registration statement. We have omitted parts of the registration statement in accordance with the rules and regulations of the SEC. For further information with respect to us and our securities, you should refer to the registration statement, including its schedules and exhibits. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, you should refer to the copy of the filed contract or document which is qualified in all respects by such reference. You may obtain copies of the registration statement from the SEC's principal office in Washington, D.C. upon payment of the fees prescribed by the SEC, or you may examine the registration statement without charge at the offices of the SEC described below.

We have filed annual, quarterly and special reports, proxy statements, and other information with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further filing information and locations of public reference rooms. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically with the SEC. Our SEC filings are available to the public on that website at http://www.sec.gov.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information that we file with it, meaning we can disclose important information to you by referring you to those documents already on file with the SEC. The information incorporated by reference is considered to be part of this prospectus. We incorporate by reference the following

documents:

1. Our annual report on Form 10-KSB for the year ended December 31, 2004, filed on March 11, 2005.

2. Our quarterly reports on Form 10-QSB for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005, filed on May 16, 2005, August 15, 2005 and November 14, 2005, respectively.

3. Our current reports on Form 8-K filed on January 25, 2005, February 3, 2005, February 9, 2005, May 4, 2005, July 13, 2005, November 1, 2005, November 2, 2005, November 29, 2005, December 9, 2005 and January 3, 2006.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference in this prospectus, at no cost. Any such request may be made by writing or telephoning us at the following address or phone number:

Corporate Secretary
DOR BioPharma, Inc.
1691 Michigan Avenue
Suite 435
Miami Beach, Florida 33139
(305) 534-3393

These documents also may be accessed through our Internet web site at www.dorbiopharma.com.

INFORMATION WITH RESPECT TO THE REGISTRANT

The information required to be disclosed in the registration statement pertaining to the Company is incorporated by reference from the documents listed as incorporated by reference in "Incorporation of Certain Documents by Reference." Such documents are being delivered with this prospectus. See "Documents Incorporated by Reference," "Prospectus Summary" and "Risk Factors".

THE FUSION TRANSACTION

General

On January 17, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day $20,000 of our common stock up to an aggregate of $6.0 million over a period of approximately 15 months, subject to earlier termination at our discretion. In our discretion under certain conditions, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. The purchase price of the shares of common stock will be equal to a price based upon the future market price of our common stock. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than $0.12.

Fusion Capital is offering for sale up to 9,962,500 shares of our common stock pursuant to this prospectus including 900,000 shares to be issued to Fusion Capital as the commitment fee and 62,500 shares to be issued to Fusion Capital as a partial expense reimbursement. In connection with entering into the agreement, we authorized the sale to Fusion Capital of 9,000,000 shares of our common stock. In the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,117,439, i.e., greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

Purchase of Shares Under the Common Stock Purchase Agreement

Under the common stock purchase agreement, on each trading day Fusion Capital is obligated to purchase a specified dollar amount of our common stock. Subject to our right to suspend such purchases at any time, and our right to terminate the agreement with Fusion Capital at any time, each as described below, Fusion Capital shall purchase on each trading day during the term of the agreement $20,000 of our common stock. This daily purchase amount may be decreased by us at any time. We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above $20,000 unless our stock price is above $0.40 per share for five consecutive trading days.

The purchase price per share is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the average of the three lowest closing sale prices of our common stock during the twelve consecutive trading days ending on the trading day immediately prior to the date of a purchase by Fusion Capital.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

The following table sets forth the amount of proceeds we would receive from Fusion Capital from the sale of 9.0 million shares of our common stock offered by this prospectus at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of 9,000,000 Shares to Fusion Capital Under the Common Stock Purchase Agreement
$0.12	$1,080,000
$0.15	$1,350,000
$0.25	$2,250,000
$0.29(1)	$2,610,000
$0.50	$4,500,000
$0.66	$6,000,000

(1) Closing sale price of our common stock on January 13, 2006.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of 9.0 million shares of our common stock. We have the right to terminate the agreement without any payment or liability to Fusion Capital at any time, including in the event that all $6.0 million shares are sold to Fusion Capital under the common stock purchase agreement. In the event we elect to issue more than the 9,962,500 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,117,439, i.e., greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules.

Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price ("floor price") of $0.12. Fusion Capital does not have the right or the obligation to purchase shares of our common stock on any trading day that the market price of our common stock is below $0.12.

Our Right To Suspend Purchases

We have the unconditional right to suspend purchases at any time for any reason effective upon one trading day's notice. Any suspension would remain in effect until our revocation of the suspension.

Our Right To Increase and Decrease the Amount to be Purchased

Under the common stock purchase agreement, Fusion Capital has agreed to purchase on each trading day during a period of approximately 15 months, $20,000 of our common stock or an aggregate of $6.0 million. We have the unconditional right to decrease the daily amount to be purchased by Fusion Capital at any time for any reason effective upon one trading day's notice.

In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. First, in respect of the daily purchase amount, we have the right to increase the daily purchase amount as the market price of our common stock increases. Specifically, for every $0.10 increase in Threshold Price (as defined below) above $.30, we have the right to increase the daily purchase amount by up to an additional $5,000. For example, if the Threshold Price is $0.50 we would have the right to increase the daily purchase amount by up to an additional $10,000. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will

be void.

In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day our shares in an amount up to $200,000, provided that our share price is above $0.60 during the ten trading days prior to that trading day. The price at which such shares would be purchased would be the lower of (i) the lowest Purchase Price (as defined above) during the previous fifteen trading days prior to the date that such purchase notice was received by Fusion Capital or (ii) the lowest sale price on the date such purchase notice was received by Fusion Capital. We may increase this amount to $400,000 and $600,000 if our share price is above $0.90 and $1.20, respectively, during the ten trading days prior to our delivery of the purchase notice to Fusion Capital. We may deliver multiple purchase notices; however at least ten trading days must have passed since the most recent non-daily purchase was completed. The daily purchases shall be suspended for ten (10) trading days each time any such notice is delivered.

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

- the effectiveness of the registration statement of which this prospectus is a part of lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereby and such lapse or unavailability continues for a period of five (5) consecutive trading days or for more than an aggregate of twenty (20) trading days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of three consecutive trading days;

- the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the New York Stock Exchange or the OTC Bulleting Board;

- the transfer agent's failure for five (5) trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the common stock purchase agreement;

- any material breach of the representations or warranties or covenants contained in the common stock purchase agreement or any related agreements which has or which could have a material adverse affect on us subject to a cure period of five (5) trading days;

    - any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;

- a material adverse change in our business, properties, operations, financial condition or results of operations; or

- the issuance of an aggregate of 10,117,439 (or 19.99% of our current shares outstanding) shares to Fusion Capital under our agreement and we fail to obtain the requisite stockholder approval.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the common stock purchase agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Effect of Performance of the Common Stock Purchase Agreement on Our Stockholders

All shares registered in this offering will be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 15 months from the date of this prospectus. The sale of a significant amount of shares registered in this offering at any given time could cause the trading price of our common stock to decline and to be highly volatile. Fusion Capital may ultimately purchase all of the 9,000,000 shares of common stock registered in this offering, and it may sell some, none or all of the shares of common stock it acquires upon purchase. Therefore, the purchases under the common stock purchase agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right at any time for any reason to: (1) reduce the daily purchase amount, (2) suspend purchases of the common stock by Fusion Capital and (3) terminate the common stock purchase agreement.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the common stock purchase agreement.

Commitment Shares Issued to Fusion Capital

Under the terms of the common stock purchase agreement we have agreed to issue to Fusion Capital 450,000 shares of our common stock as a partial commitment fee upon entering into the agreement. Those shares will be issued to Fusion Capital as soon as they are approved for listing with AMEX. Fusion Capital is also entitled to receive up to an additional 450,000 commitment shares. These additional commitment shares will be issued in an amount equal to the product of (x) 450,000 (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the dollar amount of the shares being purchased by Fusion Capital and the denominator of which is $6.0 million. Unless an event of default occurs these shares must be held by Fusion Capital until 15 months from the date of the common stock purchase agreement or the date the common stock purchase agreement is terminated or in the event that we cannot commence sales of stock to Fusion Capital prior to March 15, 2006.

No Variable Priced Financings

Until the termination of the common stock purchase agreement, we have agreed not to issue, or enter into any agreement with respect to the issuance of, any variable priced equity or variable priced equity-like securities unless we have obtained Fusion Capital's prior written consent.

SELLING STOCKHOLDER

The following table presents information regarding the selling stockholder. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us.

Selling Security Holders' Table

Name and Address of Security Holder	Common Shares Beneficially Owned Prior to Offering (1)	Total Number of Shares to be Registered (1)	Total Number of Shares held by Security Holder After Offering
Fusion Capital II, LLC (2) 22 Merchandise Mart Plaza Suite 9-112 Chicago, IL 60654	512,500	9,962,500	- 0 -

(1) We have agreed in the common stock purchase agreement to issue 512,500 shares of our common stock to Fusion Capital as a partial commitment fee and partial expense reimbursement. These shares will be issued upon approval for listing by the AMEX. Fusion Capital may acquire an additional 9,450,000 shares under the common stock purchase agreement. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

(2) Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and investment power over the Fusion Capital shares being offered under this prospectus.

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 stockholder. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to $6.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement. We intend to use the net proceeds from sales under the Common Stock Purchase Agreement as working capital to cover costs associated with the assembly and filing of the NDA for orBec®, other research and development expenses, and general overhead costs including salaries until such time, if ever, as we are able to generate a positive cash flow from operation.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder only for cash directly to one or more purchaser or

through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed.

The sale of the common stock offered by this Prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions;
- any combination of the foregoing methods of sale; and
- any other method permitted pursuant to applicable law.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholders and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Fusion Capital is an "underwriter" within the meaning of the Securities Act of 1933. Any broker-dealers or agents that are involved in selling the shares for the selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with such sales.

Neither we nor the selling stockholder can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholder, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this Prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Fusion Capital and related persons against specified liabilities, including liabilities under the Securities Act of 1933.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the common stock purchase agreement.

We have advised Fusion Capital that while it is engaged in a distribution of the shares included in this Prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this Prospectus.

This offering will terminate on the date that all shares offered by this Prospectus have been sold by the selling stockholder.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 155,000,000 shares of capital stock, of which 150,000,000 shares are common stock, par value $.001 per share, 4,600,000 shares are preferred stock, par value $.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $.05 per share and 200,000 shares are Series C Convertible Preferred Stock, par value $.05 per share. As of January 13, 2006, there were issued and outstanding 50,612,504 shares of common stock, options to purchase 10,264,339 shares of common stock and warrants to purchase 22,167,118 shares of common stock. The amount outstanding does not include 450,000 shares to be issued to Fusion as a partial commitment fee and 62,500 shares to be issued to Fusion as partial expense reimbursement, all of which will be issued as soon as those shares are approved for listing with AMEX. The amount outstanding also does not include the balance of the commitment fee to be issued to Fusion Capital.

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.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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

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

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

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

EXPERTS

Sweeney, Gates & Co., an independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-KSB for the year ended December 31, 2004 and 2003 as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in this prospectus in reliance on Sweeney, Gates & Co.'s report, given on their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the shares of our common stock offered by the Selling Stockholder will be passed upon by the law firm of Edwards Angell Palmer & Dodge LLP, Fort Lauderdale, Florida.

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	$ 287.82
Legal fees and expenses	$30,000.00
Accounting fees and expenses	$1,000.00
Miscellaneous	$ 712.18
TOTAL	$32,000.00

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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.

During February 2003, the Registrant entered into an exclusive license agreement with Thomas Jefferson University to exclusively license certain U.S. and international patent applications related to the oral administration of nontoxic modified botulinum toxins as vaccines. As part of the compensation received pursuant to the license agreement, the

Registrant issued 141,305 shares of its common stock to Jefferson University for $0.92 per share. In connection with the license agreement, the Registrant entered into a consulting agreement with Dr. Lance Simpson, the inventor of the botulinum toxin vaccine, for a period of three years under which the Registrant granted Dr. Simpson options to purchase 100,000 shares of Registrant's common stock for $0.99 per share vesting over three years. The shares of common stock and options were issued in transactions exempt from registration under the Securities Act of 1933 in reliance upon Section 4(2) of the Securities Act, as transactions not involving a public offering.

During September 2003, the Registrant completed a private placement in which it issued (i) 6,796,919 shares of common stock at $0.796 per share and (ii) warrants exercisable for 6,796,919 shares of its common stock at an exercise price of $0.8756 per share, resulting in net proceeds of approximately $4.9 million**.** The warrants have a five-year term. Also, as part of the compensation received for its assistance in the private placement, the placement agents/dealers received warrants to purchase an aggregate of 1,359,383 shares of the Registrant's common stock at an exercise price of $0.8756 per share. The shares of common stock and warrants were issued in transactions exempt from registration under the Securities Act of 1933 in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

During March 2004, the Registrant completed a private placement in which it issued (i) 4,113,924 shares of common stock at $0.79 per share and (ii) warrants exercisable for 1,645,569 shares of its common stock at an exercise price of $0.87 per share, resulting in net proceeds of approximately $3.0 million. The warrants have a five-year term. Also, as part of the compensation received for its assistance in the private placement, the placement agent received warrants to purchase an aggregate of 257,120 shares of the Registrant's common stock at an exercise price of $0.87 per share. The shares of common stock and warrants were issued in transactions exempt from registration under the Securities Act of 1933 in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

During February 2005, the Registrant completed a private placement in which it issued (i) 8,396,100 shares of common stock at $0.45 per share and (ii) warrants exercisable for 6,247,075 shares of its common stock at an exercise price of $0.505 per share, resulting in net proceeds of approximately $3.5 million. The warrants have a five-year term. Also, as part of the compensation received for its assistance in the private placement, the placement agent received warrants to purchase an aggregate of 629,708 shares of the Registrant's common stock at an exercise price of $0.625 per share. The shares of common stock and warrants were offered in transactions exempt from registration under the Securities Act of 1933 in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

ITEM 16. Exhibits.

3.1 Amended and Restated Certificate of Incorporation. (10)

3.2 By-laws. (11)

4.1 Form of Investor Warrant issued to each investor dated as of April 12, 2000. (1)

4.2 Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000. (1)

4.3 Warrant issued to Aries Fund dated as of May 19, 1997. (1)

4.4 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997. (1)

4.5 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997. (2)

4.6 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997. (2)

4.7 Warrant issued to Élan International Services, Ltd. dated January 21, 1998. (3)

4.8 Form of Warrant to be issued to CTD warrant holders. (4)

4.9 Form of Warrant issued to each investor in the December 2002 private placement.

4.10 Form of Warrant issued to each investor in the September 2003 private placement. (8)

4.11 Form of Warrant issued to each investor in the March 2004 private placement. (9)

4.12 Form of Warrant issued to each investor in the February 2005 private placement. (13)

4.13 Form of Warrant issued to Mid South Capital, Inc. in the February 2005 private placement. (14)

5.1 Opinion of Edwards Angell Palmer & Dodge LLP

10.1 Amended and Restated 1995 Omnibus Incentive Plan. (10)

10.2 Lease dated September 1, 2003 between the Company and L.N.R. Jefferson LLC.

10.3 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD. (5)

10.4 Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001. (7)

10.5 Termination of the Endorex Newco joint venture between the Company, Élan Corporation, Élan international services, and Elan Pharmaceutical dated December 12, 2002. (7)

10.6 Option Agreement with General Alexander M. Haig Jr. (7) *

10.7 Separation Agreement and General Release between the Company and Ralph Ellison dated July 9, 2004. (14)

10.8 License Agreement between the Company and The University of Texas Southwestern Medical Center. (14)

10.9 License Agreement between the Company and Thomas Jefferson University. (14)

10.10 License Agreement between the Company and The University of Texas Medical Branch. (14)

10.11 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (14)

10.12 Form of Subscription Agreement between the Company and each investor dated July 18, 2003. (8)

10.13 Form of Securities Purchase Agreement between the Company and each investor dated March 4, 2004. (9)

10.14 Form of Registration Rights Agreement between the Company and each Investor dated March 4, 2004. (9)

10.15 Employment agreement between the Company and Greg Davenport dated September 1, 2004. (14)*

10.16 Employment agreement between the Company and Mike Sember dated December 7, 2004. (14)*

10.17 Employment agreement between the Company and Evan Myrianthopoulos dated December 9, 2004. (14)*

10.18 Employment agreement between the Company and James Clavijo dated February 18, 2005. (14)*

10.19 Form of Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (13).

10.20 Amendment No. 1 dated February 17, 2005 to the Securities Purchase Agreement between the Company and each investor dated February 1, 2005. (14)

10.21 Form Registration Rights agreement between the Company and each investor dated February 1, 2005 (13).

10.22 Securities Purchase Agreement dated as of February 1, 2005 among the Company and the investors named therein. (15)

10.23 Form of Common Stock Purchase Warrant. (15)

10.24 Registration Rights Agreement dated as of February 1, 2005 among the Company and the investors named therein. (15)

10.25 Binding Letter of Intent Dated October 28, 2005 between the Company and Gastrotech. (16)

10.26 Common Stock Purchase Agreement dated January 17, 2006 between the Company and Fusion Capital. (17)

10.27 Registration Rights Agreement dated January 17, 2006 between the Company and Fusion Capital. (17)

23.1 Consent of Sweeney, Gates & Co., independent registered public accounting firm.

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

* Management contract or compensatory plan or arrangement

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(1) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000.

(2) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997.

(3) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997.

(4) Incorporated by reference to our Registration Statement on Form S-4 filed on October 2, 2001.

(5) Incorporated by reference to our current report on Form 8-K filed on December 14, 2001.

(6) Incorporated by reference to our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2001.

(7) Incorporated by reference to our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002.

(8) Incorporated by reference to our current report on Form 8-K filed on July 18, 2003.

(9) Incorporated by reference to our current report on Form 8-K filed on March 4, 2004.

(10) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003.

(11) Incorporated by reference to our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003.

(12) Incorporated by reference to our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2003.

(13) Incorporated by reference to our current report on Form 8-K filed on February 3, 2005.

(14) Incorporated by reference to our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004.

(15) Incorporated by reference to our Current Report on Form 8-K filed on February 3, 2005.

(16) Incorporated by reference to our Current Report on Form 8-K filed on November 2, 2005.

(17) Incorporated by reference to our Current Report on Form 8-K filed on January 19, 2006.

ITEM 17. Undertakings.

(a) The undersigned Registrant hereby undertakes as follows:

(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;

(ii) to reflect in the prospectus any facts or events arising after the effective date of this 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 this 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 this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, 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 this offering.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the 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 our 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 Miami, State of Florida, on the 19 day of January, 2006.

DOR BIOPHARMA, INC.

By: /s/ Michael T. Sember
Michael T. Sember
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael T. Sember 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/Michael T. Sember Michael T. Sember	Director, President and Chief Executive Officer (Principal Executive Officer)	January 19, 2006
/s/Evan Myrianthopoulos Evan Myrianthopoulos	Director, Chief Financial Officer (Principal Financial and Accounting Officer)	January 19, 2006
/s/Alexander P. Haig Alexander P. Haig	Chairman of the Board	January 19, 2006
/s/Steve H. Kanzer Steve H. Kanzer	Vice-Chairman of the Board	January 19, 2006
/s/James S. Kuo	Director	January 19, 2006

James S. Kuo		
/s/T.J. Madison T.J. Madison	Director	January 19, 2006