DOR BIOPHARMA INC
Form S-3
April 15, 2004

As filed with the Securities and Exchange Commission on April 15, 2004
Registration No. 333-[_____]

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT

Under
the Securities Act of 1933

DOR BioPharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)		41-1505029 (I.R.S. Employer Identification No.)

1691 MICHIGAN AVE, SUITE 435, MIAMI, FL, 33139, (305) 534-3383
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

WILLIAM D. MILLING

CONTROLLER, TREASURER AND CORPORATE SECRETARY
1691 MICHIGAN AVE, SUITE 435, MIAMI, FL, 33139, (305) 534-3383
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

MARK D. WOOD, ESQ.
CRAIG C. BRADLEY, ESQ.
Katten Muchin Zavis Rosenman
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3693
(312) 902-5200

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ~

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 other than securities offered only in connection with dividend or interest reinvestment plans, 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, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ~ _____

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ~ _____

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, $0.001 par value per share	6,471,241	$0. 865	$5,597,624	$710

1) Pursuant to Rule 416(a) under the Securities Act of 1933, the number of shares of common stock registered hereby is subject to adjustment to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for purposes of calculating the registration fee, pursuant to Rule 457 of Regulation C under the Securities Act of 1933, on the basis of the average of the high and low price of our common stock as reported on the American Stock Exchange on April 14, 2004.

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 of 1933 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. We 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 and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED April 15, 2004

PROSPECTUS

DOR BioPharma, Inc.
6,471,241 Shares

Common Stock

Our common stock is traded on the American Stock Exchange under the symbol "DOR." The closing sale price of our common stock on April 6, 2004 was $0.89 per share.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the "Risk Factors" beginning on page 1 before you decide whether to invest in shares of our common stock.

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 , 2004

TABLE OF CONTENTS

You should rely only on the information contained in or incorporated by reference in this prospectus and in any prospectus supplement. We have not authorized anyone else to provide you with different information, and if you receive any unauthorized information you should not rely on it. We have not authorized the selling stockholders to make an offer of these shares in any place where the offer is not permitted. You should not assume that the information in this prospectus, any supplement or any document incorporated by reference is accurate as of any date other than the date of that document.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and the documents incorporated by reference. This summary does not contain all of the information that you should consider before investing in our common stock. You should carefully revue this entire prospectus and the documents that are incorporated by reference, including the risk factors and the financial statements and related notes

The Company

We are a biopharmaceutical company focused on the development of biodefense vaccines and therapeutics for unmet medical needs. Through our biodefense division, we are developing bioengineered vaccines designed to protect against the deadly effects of exposure to ricin and botulinum toxins, both of which are considered serious bioterrorism threats. These technologies, which were exclusively licensed by us from two leading university research centers, are currently undergoing efficacy and toxicity testing in animals prior to initiating human clinical trials. Through our therapeutics division, we are developing orBec ® (oral beclomethasone dipropionate) for the treatment of intestinal inflammation associated with acute Graft-versus-Host Disease, a condition that affects a large percentage of allogeneic bone marrow transplant patients. OrBec® is an orally-delivered, potent, locally acting corticosteroid that reduces inflammation within the tissue of the gastrointestinal tract. There is currently no Food and Drug Administration approved products for the treatment of acute intestinal GvHD. OrBec® is being tested in a pivotal phase III clinical trial with the goal of filing a New Drug Application with the FDA in late 2004. We are also considering oral beclomethasone dipropionate for a number of additional therapeutic indications that involve inflammatory conditions of the gastrointestinal tract. Our business strategy is to (a) build value in our existing product candidates by efficiently advancing their development with assistance from government grants and corporate partners, and (b) grow our product portfolio through the strategic acquisition and/or in-licensing of additional clinical stage product opportunities.

The Offering

This prospectus relates to the offer and sale from to time to time of up to 6,471,241 shares of our common stock by the selling stockholders. Of the shares registered for resale through this prospectus, 6,047,469 shares were issued or are issuable in connection with our March 2004 private placement as follows: (1) 4,113,926 shares were sold to investors in the private placement; (2) 1,933,543 shares are issuable upon exercise of warrants, exercisable until March 15, 2009 at a price of $0.87 per share, sold to investors in the private placement; and (3) 287,974 shares are issuable upon exercise of warrants, exercisable until March 15, 2009 at a price of $0.87 per share, issued as consideration for placement services rendered in connection with the private placement. Of the remaining 423,772 shares registered for resale through this prospectus, 46,886 shares were issued in exchange for license rights and 376,886 shares of common stock were issued to holder of our series B preferred stock, as inducement for the voluntary early conversion of their preferred stock to common stock.

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

proceeds from the sale of shares by the selling stockholders.

Risk Factors

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

Risks Related To Our Business and 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 development stage 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. 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 March 31, 2004, we had expended approximately $3.7 million developing our current product candidates for preclinical research and development and clinical trials, and we currently have commitments to spend at least $2.5 million over the next two years in connection with development of our vaccines and therapeutic products, licenses, employee agreements, and consulting agreements. Unless and until we are able to generate 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 by our issuing equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations.

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

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

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

· that we will encounter problems in clinical trials; or

· that 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 orBec® or 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.

All of our product offerings, as well as the processes and facilities by which they are manufactured, are 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. Clinical trials of our lead product candidate orBec® began in 2001 and are expected to continue for at least three more months. We do not expect to complete clinical testing of any of our product candidates within the next three months.

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.

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 our products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

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. We have also entered into a letter of intent with the University of Texas Southwestern Medical Center, under which we plan to license issued patent and pending patent applications for technologies relating to nasal delivery of ricin vaccine. Although this letter of intent provides for defined business terms, we may not be able to come to definitive agreements with the institutions and, as a result, may not obtain critical intellectual property rights on which we expect to rely.

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. Virtually all 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 those vaccine candidates. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

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

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

We have only nine employees, we depend upon these nine 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. Furthermore, these few employees on whom our business depends have limited experience in managing and operating our business. Dr. Ralph Ellison, our Chief Executive Officer and President, was hired in March 2003; Geoff Green, our Chief Operating Officer, was hired in July 2003; Dr. Gregory Davenport, our Vice President of Business Development, was hired in December 2003; William Milling, our Controller, Treasurer and Corporate Secretary was hired in September 2002; and Dr. Robert Brey, our Chief Scientific Officer was hired in December 2002. In addition, Alexander Haig, our Chairman of the Board, was appointed in January 2003. 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. Some of our board members are associated

with other companies in the field of biopharmaceuticals and investors should not expect any obligation on the part of these directors to present opportunities to our company.

Risks Related to the offering

Our stock price is highly volatile.

The market price of our common stock, like that of many other development stage 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, which include, actual or anticipated fluctuations in our results of operations, announcements of innovations by us or our competitors, additions or departures of key personnel or general market conditions. For example, when ricin was discovered in an apartment in London and we announced that we had retained Mr. Haig as our Chairman of the Board on January 7, 2003; our stock price went from $0.58 per share to $1.05 per share in one day and has fluctuated between $0.63 per share and $1.57 per share from that date through April 07, 2004. From July 1, 2000 through April 07, 2004, the per share price of our common stock ranged from a high of $9.44 per share to a low of $0.11 per share, including a high of $2.10 per share and low of $0.11 per share since the beginning of 2002. 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 continuing operations in fiscal 2003, the stockholders equity standard applicable to us of the American Stock Exchange s continued listing requirements increased to $6 million for fiscal years ending 2003 and beyond. Moreover, our net equity of $2.3 million as of June 30, 2003 did not satisfy the $4 million minimum stockholders equity requirement 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. On August 4, 2003 we submitted a compliance plan, and the AMEX has accepted our plan and given us 18 months to regain compliance in accordance with the terms of our plan. If, however, we do not conform to our plan, or if after the 18 month period we are not in compliance with the minimum listing requirements, we may be delisted from the AMEX. Furthermore, we cannot 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 for any reason, 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 15.4 million shares of our common stock at a current weighted average exercise price of approximately $ 1.40;

· 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 8.5 million shares of our common stock of a current weighted average exercise price of approximately $0.72.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference in it contains, or will contain, various "forward-looking statements" that are based on management s beliefs, as well as assumptions made by, and information currently available to, management, including statements regarding future economic performance, financial condition, liquidity and capital resources, acceptance of our products and services by the market and management s objectives. Where possible, we have tried, and will try, to identify the forward-looking statements by using words such as "anticipates," "expects," "believes," "estimates," "plans," "intends" and similar expressions. These statements are subject to various risks, uncertainties and other factors that could cause our actual results, performance and achievements to differ materially from those expressed in, or implied by, these statements. These risks, uncertainties and other factors include the risk factors discussed above, in any prospectus supplement and in any document incorporated by reference into this prospectus. You should not place any undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to update any forward-looking statements to reflect new information, future events or developments or changes of circumstances or for any other reason.

USE OF PROCEEDS

Any net proceeds from any sale of shares of our common stock covered by this prospectus will be received by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

SELLING STOCKHOLDERS

Of the 6,471,241 shares of our common stock registered for public resale pursuant to this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 6,047,469 shares were issued or are issuable in connection with our March 2004 private placement, in which we sold shares at $0.79 per share, with investors receiving warrants to purchase 0.4 shares of common stock with an exercise price of $0.87, with each share purchased. This placement was completed on March 15, 2004. These shares of our common stock are included in this prospectus pursuant to registration rights we granted in connection with the March 2004 private placement.

Of the remaining 423,772 shares of our common stock registered for public resale pursuant to this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 46,886 shares were issued to The Board of Regents of the University of Texas system and their designees in exchange for a license to certain ricin technology and 376,886 shares were issued to Élan Pharmaceutical Investments, Ltd. as an inducement for the voluntary early conversion of all their shares of our Series B Preferred Stock to common stock. These shares of our common stock are included in this prospectus pursuant to the registration rights we granted in connection with these license agreements and our agreement with Élan Pharmaceutical Investments, Ltd.

The following table sets forth the number of shares beneficially owned by each of the selling stockholders as of the date of this prospectus. We are not able to estimate the amount of shares that will be held by each selling stockholder after the completion of this offering because: (1) the selling stockholders may sell less than all of the shares registered under this prospectus; (2) the selling stockholders may exercise less than all of their warrants; and (3) to our knowledge, the selling stockholders currently have no agreements, arrangements or understandings with respect to the sale of any of their shares. The following table assumes that all of the currently outstanding warrants will be exercised into common stock and all of the shares being registered pursuant to this prospectus will be sold. The selling stockholders are not making any representation that any shares covered by this prospectus will be offered for sale. Except as otherwise indicated, based on information provided to us by each selling stockholder, the selling stockholders have sole voting and investment power with respect to their shares of common stock.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Before the Offering (1)	Percent of Common Stock Owned Before the Offering	Shares Available for Sale Under This Prospectus (1)	Number of Shares of Common Stock To Be Owned After Completion of the Offering	Percent of Common Stock to be Owned After Completion of the Offering
SF Capital Partners Ltd.	3,544,305	8.23%	3,544,305	-	*
RHP Master Fund, Ltd.	886,076	2.10%	886,076	-	*
Castle Creek Healthcare Partners, LLC	443,038	1.05%	443,038	-	*
CC Life Science, Ltd.	443,038	1.05%	443,038	-	*
Provident Premier Master Fund, Ltd (2)	443,038	1.05%	443,038	-	*
Hefcap Holdings, LLC (3)	86,392	*	86,392	-	*
Marc C. Tesio (4)	115,190	*	115,190	-	*
	86,392	*	86,392	-	*

Windward Capital Advisors, LLC (5)					
Élan Pharmaceutical Investments, Ltd.	3,044,556	7.24%	376,886	2,667,670	6.35%
The Board of Regents of the University of Texas system	197,500	*	37,040	160,460	*
Roxana G. Baluma (6)	25,000	*	4,689	20,311	*
Joan E. Smallshaw (6)	22,500	*	4,220	18,280	*
Michelle Vitteta (6)	5,000	*	937	4,063	*

*Less than 1%.

(1) Includes shares of common stock initially issuable upon the exercise of warrants as follows: SF Capital Partners Ltd., 1,012,659 shares; RHP Master Fund, Ltd., 253,164 shares; Castle Creek Healthcare Partners, LLC, 126,582 shares; CC Life Science, Ltd., 126,582 shares; Provident Premier Master Fund, Ltd., 126,582 shares; Hefcap Holdings, LLC, 86,392 shares; Marc C. Tesio, 115,190 shares; and Windward Capital Advisors, LLC, 86,392 shares. The holders of these warrants may not exercise the warrants into shares of our common stock if after the exercise, such holder, together with its affiliates, would beneficially own over 4.999% of the outstanding shares of our common stock. The 4.999% limitation would not prevent the holder from acquiring and selling in excess of 4.999% of our common stock through a series of exercises. This provision may be waived by the holder (but only as to itself and not as to any other holder) upon not less than 61 days prior notice to the Company. Other holders shall be unaffected by any such waiver. The holders of these warrants may not exercise the warrants into shares of our common stock if after the exercise, such holder, together with its affiliates, would beneficially own over 9.999% of the outstanding shares of our common stock. The 9.999% limitation would not prevent the holder from acquiring and selling in excess of 9.999% of our common stock through a series of exercises. This restriction may not be waived.

(2) The number of shares listed under the caption "Number of Shares of Common Stock Owned Before the Offering" includes 126,582 shares of common stock issuable upon exercise of warrants issued in connection with our March 2004 private placement, with an exercise price per shares of $0.87. Steven Winters, managing member of Gemini Investment Strategies, LLC, a trading manager of the listed fund, has investment control over these securities. Mr. Winters has represented to us that he disclaims beneficial ownership of the securities.

(3) Hefcap Holdings, LLC is an owner of Cardinal Securities, LLC, a NASD broker dealer and placement agent for the transaction. Robert L. Rosenstein is

the principal of Hefcap Holdings, LLC and has investment control over these shares.

(4) Marc Tesio is a registered representative of Cardinal Securities, LLC, member NASD.

(5) Windward Capital Advisors, LLC is an owner of Cardinal Securities, LLC, a NASD broker dealer and placement agent for the transaction. H. David Coherd is the principal of Windward Capital Advisors, LLC and has investment control over these shares.

(6) Designees of the Board of Regents of the University of Texas System.

PLAN OF DISTRIBUTION

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

· ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

· block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

· purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

· an exchange distribution in accordance with the rules of the applicable exchange;

· privately negotiated transactions;

· to cover short sales and other hedging transactions made after the date that this registration statement is a part was declared effective by the SEC;

· broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

· face-to-face transactions between sellers and purchasers without a broker-dealer;

· by writing options, whether such options are listed on an options exchange or otherwise;

· a combination of any such methods of sale; and

· any other method permitted pursuant to applicable law.

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

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

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

Upon our being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon our being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

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

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

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

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

WHERE YOU CAN FIND MORE INFORMATION

We file 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 rooms at Judiciary Plaza Building, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. Copies of these materials may also be obtained from the SEC at prescribed rates by writing to the Public Reference Section of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information about the operation of the SEC public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. Our filings are also available to the public from commercial document retrieval services and at the web site maintained by the SEC at http://www.sec.gov.

This prospectus is part of a registration statement we have filed with the SEC. The SEC allows us to incorporate documents by reference. This means that we can disclose important information by referring you to another document we file separately with the SEC. The information incorporated by reference is considered to be part of this prospectus, except for any information superseded by information in this prospectus. The information we file later with the SEC will automatically update and supersede the information contained in this prospectus or incorporated by reference from earlier filings. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until all of the securities covered by this prospectus have been sold or we have deregistered all of the securities then remaining unsold:

· Our annual report on Form 10-KSB for the year ended December 31, 2003, as amended by a Form 10-KSB/A filed on April 15, 2004;

· Our current reports on Form 8-K dated: January 16, 2004, March 4, 2004, and March 15, 2004; and

· The description of our common stock contained in the registration statement on Form 8-A dated August 4, 1998 filed under the Securities Exchange Act of 1934, and all amendments and reports filed by us to update the description.

You may request a copy of these filings, at no cost, by writing or telephoning us at our principal executive offices at the following address and phone number:

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

LEGAL MATTERS

The legality of the securities offered hereby has been passed upon for us by Katten Muchin Zavis Rosenman, Chicago, Illinois.

EXPERTS

Our consolidated financial statements appearing in our Annual Report on Form 10-KSB as amended for the year ended December 31, 2003, have been audited by Sweeney, Gates & Co., independent certified public accountants, as set forth in their report thereon, included therein and incorporated herein by reference. These consolidated financial

statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. 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.

Securities and Exchange Commission registration fee.	$ 710
Legal fees and expenses.	4,000
Accounting fees and expenses.	2,000
Miscellaneous expenses.	1,290
Total expenses.	$ 8,000

ITEM 15. Indemnification of Directors and Officers.

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

Section 145 of the Delaware General Corporation Law grants to the small business issuer the power to indemnify its directors, officers, employees and agents against liability arising out of their respective capacities as directors, officers, employees or agents. Article VIII of the small business issuer s Bylaws provide that the small business issuer shall indemnify any person who is serving as a director, officer, employee or agent of the small business issuer, or of another entity at the request of the small business issuer, against judgments, fines, settlements and other expenses incurred in such capacity if such person acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the small business issuer and, with respect to any criminal action, had no reasonable

cause to believe his conduct was unlawful. In the event of an action or suit by or in the right of the small business issuer, no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for negligence or misconduct in the performance of his duty to the small business issuer unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court shall deem proper.

The small business issuer has entered into indemnification agreements with its directors that would require the small business issuer, subject to any limitations on the maximum permissible indemnification that may exist at law, to indemnify a director for claims that arise because of his service as a director.

The small business issuer has a directors and officers liability insurance policy.

The above discussion is qualified in its entirety by reference to the small business issuer s Certificate of Incorporation and Bylaws and the form of the indemnification agreement with directors.

ITEM 16. Exhibits

Exhibit Number	Exhibit
4.1	Amended and Restated Certificate of Incorporation, incorporated by reference from Exhibit 3.1 to the registrant s quarterly report on Form 10-QSB for the fiscal quarter ended September 30, 2003.
4.2	Amended and Restated Bylaws of the Company, incorporated by reference from Exhibit 3.1 to the registrant s quarterly report on Form 10-QSB for the fiscal quarter ended June 30, 2003.
5.1	Opinion of Katten Muchin Zavis Rosenman as to the validity of the common stock.
23.1*	Consent of Sweeney, Gates & Co., independent certified public accountants.
23.2*	Consent of Katten Muchin Zavis Rosenman (contained in its opinion filed as Exhibit 5.1 hereto).
24.1*	Powers of Attorney (included on the signature page hereto).

* Filed herewith

ITEM 17. Undertakings

A. The small business issuer hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement to include any additional or changed material information on the plan of distribution.

(2) To, for determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement relating to the securities offered therein, and the offering of the securities at that time to be the initial bona fide offering.

(3) To file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

1. Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the SEC 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 small business issuer of expenses incurred or paid by a director, officer or controlling person of the small business issuer 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 small business issuer will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 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 15 th day of April, 2004.

DOR Biopharma, Inc.
By: /s/ Ralph M. Ellison
Ralph M. Ellison
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Ralph M. Ellison and William D. Milling, and each of them severally, acting along and without the other, his true and lawful attorneys-in-fact and agents, with full power of substitution, to sign on his behalf, individually and in each capacity stated below, all amendments and

post-effective amendments to this registration statement and any registration statement registering additional securities pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and any other documents in connection therewith, with the Securities and Exchange Commission under the Securities Act of 1933, 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 each might or could do in person, hereby ratifying and confirming each act that said attorneys-in-fact and agents may lawfully do or cause to be done by virtue thereof.

SIGNATURES

Pursuant to the requirements of the 1933 Act, this registration statement has been signed below on April 15, 2004 by the following persons in the capacities indicated.

Signature	Title
/s/ General Alexander M. Haig, Jr. General Alexander M. Haig, Jr.	Chairman of the Board
/s/ Ralph M. Ellison Ralph M. Ellison	Chief Executive Officer, President and Director (principal executive officer)
/s/ Steve M. Kanzer Steve M. Kanzer	Vice-Chairman of the Board
/s/ William D. Milling William D. Milling	Controller, Treasurer and Corporate Secretary (principal financial and accounting officer)
/s/ Larry Kessel Larry Kessel	Director
/s/ Arthur Asher Kornbluth Arthur Asher Kornbluth	Director
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Director
/s/ Peter Salomon Peter Salomon	Director
/s/ James S. Kuo James S. Kuo	Director
/s/ Stuart Sedlack Stuart Sedlack	Director

INDEX TO EXHIBITS

Exhibit Number	Exhibit
5.1	Opinion of Katten Muchin Zavis Rosenman as to the validity of the common stock.
23.1	Consent of Sweeney, Gates & Co., independent certified public accountants.
23.2	Consent of Katten Muchin Zavis Rosenman (contained in its opinion filed as Exhibit 5.1 hereto).
24.1	Power of Attorney (included on the signature page hereto).