DOR BIOPHARMA INC
Form 424B3
April 06, 2005

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Registration No.: 333-123281

**DOR BioPharma, Inc.**

**15,922,883 Shares of
Common Stock**

This prospectus relates to the resale, from time to time, of up to 15,922,883 shares of our common stock, by the selling stockholders named in this prospectus in the section “Selling Stockholders,” including their pledges, assignees and successors-in-interest, whom we collectively refer to in this document as the “Selling Stockholders.” On February 9, 2005, we consummated a financing pursuant to which we issued to the Selling Stockholders (i) 8,396,100 shares of common stock and (ii) warrants to purchase up to an aggregate of 7,526,783 shares of common stock (the “Warrants”). The common stock being offered in this prospectus may include shares issued pursuant to the exercise of the Warrants. The common stock offered by this prospectus shall be adjusted to cover any additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions. We will not receive any of the proceeds from the sale of any of the shares covered by this prospectus. References in this prospectus to “the Company,” “we,” “our,” and “us” refer to DOR BioPharma, Inc.

Our common stock is traded on the American Stock Exchange under the symbol "DOR." On April 5, 2005, the last reported sale price for our common stock was $0.42 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 3 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 April 6, 2005

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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 Stockholders to make an offer of these shares of common stock in any jurisdiction where the offer is not permitted.**

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

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## 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;
- our ability to obtain future financing or funds when needed;
- 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 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; and
- maintenance of a successful business strategy.

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 research and development of biodefense vaccines and oral therapeutic products intended for areas of unmet medical need. We were incorporated in 1987. We maintain two active segments: BioDefense and BioTherapeutics.

Through our BioDefense Division, we are developing bioengineered countermeasure vaccines for ricin toxin and botulinum toxin, both of which are considered bioterrorism threats by the U.S. Department of Homeland Security (DHS), National Institute of Allergic and Infectious Diseases (NIAID), Department of Defense (DOD) and Centers for Disease Control and Prevention (CDC). We are developing our biodefense countermeasures for potential U.S. government procurement pursuant to the Project Bioshield Act of 2004, which provides incentives to industry to expeditiously supply biodefense countermeasures to the Strategic National Stockpile. As a step towards this goal, on September 13, 2004, we were awarded a $5.2 million grant from the National Institute of Allergy and Infectious Diseases (NIAID) for RiVax™, our genetically engineered vaccine against ricin toxin, one of the most lethal plant toxins known to man. The grants project period is September 15, 2004 to August 31, 2007 and covers the process development for manufacturing of RiVax™ our recombinant vaccine for ricin toxin. The grant is based on milestones and certain budget amounts are earned as we meet certain milestones in the development of RiVax™. In addition, on February 7, 2005, we announced that our academic partner, The University of Texas Southwestern Medical Center at Dallas, began a Phase I clinical trial of RiVax™ in normal volunteers. This is the first time a ricin toxin vaccine will be studied in humans. Also, on January 7, 2005, we announced an agreement with Cambrex corporation (NYSE: CBM) on the consummation of an agreement for the process development and potential large scale production of RiVax™ covered by the aforementioned grant.

Our vaccine against botulinum neurotoxin, one of the most lethal substances known to man, BT-VACC™, is an orally administered vaccine that protects against exposure to botulinum neurotoxins. As opposed to injectable vaccines that require multiple injections, BT-VACC™ is being developed as a multivalent, solid oral dosage form. BT-VACC™ is covered by issued and pending U.S. patents that broadly claim orally deliverable botulinum neurotoxin vaccines. The oral formulation is designed to be sufficiently stable for stockpiling and storage, which is ideal for rapid distribution and vaccination for military use or civilian vaccination in response to bioterrorism. Oral administration of BT-VACC™ for serotype A produces protective antibodies that afford protection or prolonged survival of treated animals exposed to 30,000 times the lethal dose of botulinum toxin serotype A. Pre-clinical studies of BT-VACC™ for serotype B are also ongoing. On February 16, 2005, we expanded our biodefense product line from prophylactic (pre-exposure) vaccines into post-exposure therapeutics when we initiated a rational drug design program intended to identify small molecules capable of blocking the deadly effects of botulinum toxin on a post-exposure basis.

Through our BioTherapeutics Division, we are in the process of developing oral therapeutic products to treat unmet medical needs. Our therapeutic product, orBec® (oral beclomethasone dipropionate), has recently completed a pivotal Phase III clinical trial for the treatment of acute intestinal graft-vs-host disease (iGVHD), a form of serious and life-threatening gastrointestinal inflammation. On December 30, 2004, we announced top line results of 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 it's 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 70% reduction in mortality compared to placebo (p-value 0.007). orBec® is a highly potent, topically-active glucocorticoid. orBec® has previously been granted Fast Track Designation and received Orphan Drug Designation by the Food and Drug Administration (FDA) for the treatment of iGVHD. We are currently in discussions with the FDA to determine the next steps for orBec® and pending the outcome of these discussions, expect to be in a position to offer guidance in second quarter 2005.

**The Offering**

This prospectus relates to the offer and sale from to time to time of up to 15,922,883 shares of our common stock by the Selling Stockholders. Of the shares registered for resale through this prospectus, 15,322,883 shares were issued or are issuable in connection with our February 2005 private placement as follows: (1) 8,396,100 shares were sold to investors in the private placement, (2) 6,297,075 shares are issuable upon exercise of warrants, exercisable for a period of five years commencing on August 8, 2005 at a price of $0.505 per share, sold to investors in the private placement, and (3) 629,708 shares are issuable upon exercise of a warrant, exercisable for a period of five years commencing on August 8, 2005 at a price of $0.625 per share, issued to the placement agent of the private placement, Growth Capital Partners, LLC through its NASD affiliate, MidSouth Capital, Inc. Of the remaining 600,000 shares registered for resale through this prospectus, warrants to purchase 600,000 shares were issued in connection with an amendment to a consulting agreement and a stock purchase agreement.

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 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 December 31, 2004, we had $2.3 million in cash available. As a result of our private placement in February 2005, which brought in gross proceeds of approximately $3.77 million, we expect to have enough funds to meet our anticipated cash needs for the next 12 months. In addition, through the NIH 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 December 31, 2004, we had expended approximately $6.3 million developing our current product candidates for preclinical research and development and clinical trials, and we currently have commitments to spend at least $7.1 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 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.

***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:

- that 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;
- 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 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. 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 70% reduction in mortality compared to placebo. We plan to continue discussions with the FDA to determine the next steps in the development of orBec®. 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 and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the two animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the two animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

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

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

***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 nine employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. Furthermore, these few employees on whom our business depends have limited experience in managing and operating our business. 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; Dr. Gregory Davenport, the President of BioDefense Division, was hired in December 2003; 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. In addition, our President and Acting Chief Executive Officer, Geoff Green and our Controller, William Milling, resigned in the fourth quarter of 2004. 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.

**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 stock price has fluctuated between January 1, 2001 through December 31, 2004, the per share price of our common stock ranged between a high of $2.10 per share to a low of $0.11 per share. As of March 2, 2005 our common stock traded at $0.43. 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 2004, the stockholders' equity standard applicable to us of the American Stock Exchange's (AMEX) continued listing requirements is $6 million. As of February 7, 2005 on the raising of approximately $3.77 million through a private equity placement we were in compliance with the standard. However in order to continue to be in compliance with the listing standard we must execute the compliance plan submitted on December 30, 2004 with AMEX and approved by them on January 19, 2005. Despite our current compliance, AMEX may require that we also demonstrate continued compliance with all listing requirements by July 12, 2005, including minimum stockholders' equity of at least $6 million at such time. Based upon our forecasted cash expenditures, we may not satisfy such requirement at such time absent one or more transactions having the effect of increasing our current stockholders' equity.

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. 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. However, 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 22.4 million shares of our common stock at a current weighted average exercise price of approximately $1.04;

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

- options to purchase approximately 11.8 million shares of our common stock of a current weighted average exercise price of approximately $0.64.

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.

## 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 15,922,883 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, 14,693,175 shares were issued or are issuable in connection with our February 2005 private placement, in which we sold shares at $0.45 per share, with investors receiving warrants to purchase shares of common stock with an exercise price of $0.505 per share. Our placement agent, Growth Capital Partners, LLC through its NASD affiliate, MidSouth Capital, Inc., received a warrant to purchase 629,708 shares of common stock at $0.625 per share. This placement was completed on February 9, 2005. These shares of our common stock are included in this prospectus pursuant to registration rights we granted in connection with the February 2005 private placement.

Of the remaining 600,000 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, warrants to purchase 600,000 shares were issued to George B. McDonald, M.D. in connection with an amendment to his consulting agreement and a stock purchase agreement. These shares of our common stock are included in this prospectus pursuant to the registration rights we granted in connection with such amendment and stock purchase.

The following table presents information as of March 2, 2005 and 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)(2)** | **Percent of Common Stock Owned Before the Offering** | **Shares Available for Sale Under This Prospectus (2)** | **Number of Shares of Common Stock To Be Owned After Completion of the Offering** | **Percent of Common Stock to be Owned After Completion of the Offering** |
|---|---|---|---|---|---|
| SF Capital Partners Ltd.(3) | 3,581,581 | 6.73% | 3,885,000 | 2,374,240 | 4.46% |
| Silverback Master Ltd.(4) | 2,564,932 | 4.99% | 3,108,000 | - | * |
| Portside Growth and Opportunity Fund(5) | 2,100,000 | 4.08% | 2,100,000 | - | * |
| Enable Growth Partners LP(6) | 1,050,000 | 2.06% | 1,050,000 | - | * |
| Nite Capital LP(7) | 1,050,000 | 2.06% | 1,050,000 | - | * |
| Castle Creek Healthcare Partners, LLC(8) | 968,038 | 1.90% | 525,000 | 443,038 | * |
| CC LifeScience Ltd.(9) | 968,038 | 1.90% | 525,000 | 443,038 | * |
| Omicron Master Trust(10) | 875,000 | 1.72% | 875,000 | - | * |
| Silverback Life Sciences Master Fund(4) | 777,000 | 1.53% | 777,000 | - | * |
| MidSouth Capital, Inc. (11) | 629,708 | 1.23% | 629,708 | - | * |
| Cranshire Capital, L.P.(12) | 525,000 | 1.03% | 525,000 | - | * |
| Steven Mark IRA | 140,000 | * | 140,000 | - | * |
| Vasili and Elisabeth Myrianthopoulos, JTWROS | 58,625 | * | 58,625 | - | * |
| Lloyd Brokaw IRA | 35,000 | * | 35,000 | - | * |
| Francis A. and Nicole Bartul, JTWROS | 20,125 | * | 20,125 | - | * |
| Alexander and Suzanne Myrianthopoulos, JTWROS | 19,425 | * | 19,425 | - | * |
| George B. McDonald, M.D. | 600,000 | 1.17% | 600,000 | - | * |

*Less than 1%.

(1) This column does not include certain shares of common stock issuable upon exercise of warrants held by SF Capital Partners Ltd. and Silverback Master Ltd., because such warrants are subject to conversion limitations that preclude SF Capital Partners Ltd. and Silverback Master Ltd. from utilizing its exercise rights to the extent that it would beneficially own (determined in accordance with Section 13(d) of the Exchange Act) in excess of 4.99% of the total number of our issued and outstanding shares of common stock. Such limitations may be waived by providing 61 days' prior written notice to us.

(2) The shares of common stock issuable upon the exercise of warrants as follows: SF Capital Partners Ltd., 1,665,000 shares; Silverback Master Ltd., 1,332,000 shares; Portside Growth and Opportunity Fund, 900,000 shares; Enable Growth Partners LP, 450,000 shares; Nite Capital, LP, 450,000 shares; Omicron Master Trust, 375,000 shares; Silverback Life Sciences Master Fund, 333,000 shares; Castle Creek Healthcare Partners, LLC, 225,000 shares; CC Life Science Ltd., 225,000 shares; Cranshire Capital, L.P., 225,000 shares; MidSouth Capital, Inc., 629,708 shares; Steven Mark IRA, 60,000 shares; Vasili and Elisabeth Myrianthopoulos, 25,125 shares; Lloyd Brokaw IRA, 15,000 shares; Francis A. and Nicole Bartul, JTWROS, 8,625 shares; Alexander and Suzanne Myrianthopoulos, JTWROS, 8,325 shares; and George B. McDonald, M.D., 600,000 shares.

(3) The number of shares listed under the caption "Number of Shares of Common Stock Owned Before the Offering" includes 1,361,581 shares of common stock in connection with our March 2004 private placement. Michael A. Roth and Brian J. Stark are Managing Members of Stark Offshore Management, LLC ("Stark Offshore"), which acts as investment manager and has sole power to direct the management of SF Capital Partners Ltd. Through Stark Offshore, Michael A. Roth and Brian J. Stark possess voting and dispositive power over the securities held by SF Capital Partners Ltd. Michael A. Roth and Brian J. Stark disclaim beneficial ownership of the securities held by SF Capital Partners Ltd.

(4) Silverback Asset Management, LLC ("SAM") serves as investment manager to Silverback Master, Ltd. ("Silverback Master") and Silverback Life Sciences Master Fund ("Silverback Life Sciences"). In that capacity, SAM may be deemed to be the beneficial owner of securities held by Silverback Master and Silverback Life Sciences. SAM disclaims beneficial ownership of the securities held by Silverback Master and Silverback Life Sciences. Elliot Bossen is the sole Managing Member of SAM and is primarily responsible for the investment decisions of SAM. Elliot Bossen disclaims beneficial ownership of the securities held by Silverback Master and Silverback Life Sciences.

(5) Ramius Capital Group, LLC ("Ramius Capital") is the investment adviser of Portside Growth and Opportunity Fund ("Portside") and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the shares held by Portside. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S & Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these shares.

(6) Mitch Levine, Managing Partner of Enable Growth Partners LP, exercises sole voting and investment power of the shares of our common stock on behalf of this Selling Stockholder.

(7) Keith Goodman, Manager of the General Partner of Nite Capital, LP exercises sole voting and investment power of the shares of our common stock on behalf of this Selling Stockholder.

(8) The number of shares listed under the caption "Number of Shares of Common Stock Owned Before the Offering" includes 316,456 shares of common stock and 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. As investment manager under a management agreement, Castle Creek Partners, LLC may exercise dispositive and voting power with respect to the shares owned by Castle Creek Healthcare Partners LLC. Castle Creek Partners, LLC disclaims beneficial ownership of such shares. Daniel Asher is the managing member of Castle Creek Partners, LLC.

Mr. Asher disclaims beneficial ownership of the shares owned by Castle Creek Healthcare Partners LLC.

(9) The number of shares listed under the caption "Number of Shares of Common Stock Owned Before the Offering" includes 316,456 shares of common stock and 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.

(10) Omicron Capital, L.P., a Delaware limited partnership (“Omicron Capital”), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda (“Omicron”), Omicron Capital, Inc., a Delaware corporation (“OCI”), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited (“Winchester”) serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. No other person has sole or shared voting or dispositve power with respect to the shares of our common stock being offered by Omicron, as those terms are used for the purposes of Regulation 13D-G under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Omicron and Winchester are not “affiliates” of one another, as that term is used for purposes of the Exchange Act, or of any other person named in this prospectus as a Selling Stockholder. No person or “group” (as that term is used in Section 13(d) or Regulation 13D - G of the Exchange Act) controls Omicron and Winchester.

(11) Growth Capital Partners, LLC through its NASD affiliate, MidSouth Capital, Inc. is a broker-dealer who acted as placement agent for the private placement completed on February 9, 2005. We issued MidSouth warrants to purchase an aggregate of 629,708 shares of common stock at $0.625 per share, and paid $189,158 in cash as placement agent fees.

(12) Mitchell P. Kopin, President of Downsview Capital, Inc., the General Partner of Cranshire Capital, L.P., exercises sole voting and investment power of the shares of our common stock on behalf of this Selling Stockholder.

## PLAN OF DISTRIBUTION

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

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

· a combination of any such methods of sale; and

· any other method permitted pursuant to applicable law.

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

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

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act 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. The Company has advised each Selling Stockholder that it may not use shares registered on the registration statement of which this prospectus is a part to cover short sales of our common stock made prior to the date on which such registration statement was declared effective by the SEC.

We are required to pay certain fees and expenses incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may

be resold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect and (ii) such time as all of the shares have been publicly sold.

## LEGAL MATTERS

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

## EXPERTS

Sweeney, Gates & Co., independent Registered public accounting firm, have audited our consolidated financial statements included in our Annual Report on Form 10-KSB, as amended, for the year ended December 31, 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 reliance on Sweeney, Gates & Co.'s report, given on their authority as experts in accounting and auditing.

## 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 room at 450 Fifth Street, N.W., 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 Exchange Act 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, 2004, filed on March 11, 2005; and

- The description of our common stock contained in our registration statement on Form 8-A, as filed with the SEC on August 4, 1998, and any amendment and report subsequently filed by us for the purpose of updating that 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